

107TH CONGRESS
1ST SESSION

H. R. 2180

To amend the Federal Food, Drug, and Cosmetic Act to grant the Secretary of Health and Human Services the authority to regulate tobacco products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 14, 2001

Mr. TOM DAVIS of Virginia (for himself, Mr. GILLMOR, Mr. GREEN of Wisconsin, Mr. SWEENEY, Ms. GRANGER, Mr. TOWNS, Mr. LINDER, Mr. FERGUSON, Mr. COLLINS, Mr. SCHROCK, Mrs. BONO, Mr. PETERSON of Minnesota, Mr. GRUCCI, Mr. TERRY, and Mr. DOYLE) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to grant the Secretary of Health and Human Services the authority to regulate tobacco products, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “National Youth Smok-
5 ing Reduction Act”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds the following:

3 (1) The use of tobacco products by the Nation's
4 children is a pediatric disease of epic proportions
5 that results in new generations of tobacco-dependent
6 children and adults.

7 (2) A consensus exists within the scientific and
8 medical communities that tobacco products are in-
9 herently dangerous and cause cancer, heart disease,
10 and other serious adverse health effects.

11 (3) Nicotine is addictive.

12 (4) Virtually all new users of tobacco products
13 are under the minimum legal age to purchase such
14 products.

15 (5) Tobacco advertising and marketing con-
16 tribute significantly to the use of nicotine-containing
17 tobacco products by adolescents.

18 (6) Because past efforts to restrict advertising
19 and marketing of tobacco products have failed ade-
20 quately to curb tobacco use by adolescents, com-
21 prehensive restrictions on the sale, promotion, and
22 distribution of such products are needed.

23 (7) Federal and State governments have lacked
24 the legal and regulatory authority and resources
25 they need to address comprehensively the public

1 health and societal problems caused by the use of to-
2 bacco products.

3 (8) Federal and State public health officials,
4 the public health community, and the public at large
5 recognize that the tobacco industry should be subject
6 to ongoing oversight.

7 (9) Under article I, section 8 of the Constitu-
8 tion, the Congress is vested with the responsibility
9 for regulating interstate commerce and commerce
10 with Indian tribes.

11 (10) The sale, distribution, marketing, adver-
12 tising, and use of tobacco products are activities in
13 and substantially affecting interstate commerce be-
14 cause they are sold, marketed, advertised, and dis-
15 tributed in interstate commerce on a nationwide
16 basis, and have a substantial effect on the Nation's
17 economy.

18 (11) The sale, distribution, marketing, adver-
19 tising, and use of such products substantially affect
20 interstate commerce through the health care and
21 other costs attributable to the use of tobacco prod-
22 ucts.

23 (12) It is in the public interest for Congress to
24 adopt comprehensive public health legislation be-
25 cause of tobacco's unique position in the Nation's

1 history and economy and the need to prevent the
2 sale, distribution, marketing and advertising of to-
3 bacco products to persons under the minimum legal
4 age to purchase such products.

5 (13) The public interest requires a timely, fair,
6 equitable, and consistent result that will serve the
7 public interest by restricting throughout the Nation
8 the sale, distribution, marketing, and advertising of
9 tobacco products only to persons of legal age to pur-
10 chase such products.

11 (14) Public health authorities estimate that the
12 benefits to the Nation of enacting Federal legislation
13 to accomplish these goals would be significant in
14 human and economic terms.

15 (15) Reducing the use of tobacco by minors by
16 50 percent would prevent well over 60,000 early
17 deaths each year and save up to \$43 billion each
18 year in reduced medical costs, improved productivity,
19 and the avoidance of premature deaths.

20 (16) Advertising, marketing, and promotion of
21 tobacco products have been especially directed to at-
22 tract young persons to use tobacco products and
23 these efforts have resulted in increased use of such
24 products by youth. Past efforts to oversee these ac-

1 activities have not been successful in adequately pre-
2 venting such increased use.

3 (17) Tobacco advertising increases the size of
4 the tobacco market by increasing consumption of to-
5 bacco products including increasing tobacco use by
6 young people.

7 (18) Children are more influenced by tobacco
8 advertising than adults and they smoke the most ad-
9 vertised brands.

10 (19) Tobacco company documents indicate that
11 young people are an important and often crucial seg-
12 ment of the tobacco market.

13 (20) Advertising restrictions will have a positive
14 effect on the smoking rates of young people.

15 (21) Restrictions on advertising are necessary
16 to prevent unrestricted tobacco advertising from un-
17 dermining legislation prohibiting access to young
18 people.

19 (22) It is in the public interest for Congress to
20 adopt legislation to address the public health crisis
21 created by actions of the tobacco industry.

22 **SEC. 3. DEFINITIONS.**

23 (a) FEDERAL CIGARETTE LABELING AND ADVER-
24 TISING ACT.—Section 3(1) of the Federal Cigarette La-
25 beling and Advertising Act is amended—

- 1 (1) in subparagraph (A) by striking “and”;
- 2 (2) in subparagraph (B) by striking the period
- 3 and inserting “; and”; and
- 4 (3) by inserting the following new subparagraph
- 5 at the end thereof:

6 “(C) any tobacco product, in any form, in-

7 cluding bidis and kreteks, if the tobacco in the

8 product is heated or burned and is functional in

9 the product, and the product, because of its ap-

10 pearance, the type of tobacco used in the filler,

11 or its packaging and labeling, is likely to be of-

12 fered to, or purchased by, consumers as a ciga-

13 rette or as roll-your-own tobacco.”.

14 (b) THIS ACT.—In this Act:

15 (1) BRAND.—The term “brand” means a vari-

16 ety of tobacco product distinguished by the tobacco

17 used, tar content, nicotine content, flavoring used,

18 size, filtration, or packaging, logo, registered trade-

19 mark or brand name, identifiable pattern of colors,

20 or any combination of such attributes.

21 (2) CIGARETTE.—The term “cigarette” has the

22 meaning given that term by section 3(1) of the Fed-

23 eral Cigarette Labeling and Advertising Act (15

24 U.S.C. 1332(1)).

1 (3) CIGARETTE TOBACCO.—The term “cigarette
2 tobacco” means any product that consists of loose
3 tobacco that is intended for use by consumers in a
4 cigarette. Unless otherwise stated, the requirements
5 for cigarettes shall also apply to cigarette tobacco.

6 (4) COMMERCE.—The term “commerce” has
7 the meaning given that term by section 3(2) of the
8 Federal Cigarette Labeling and Advertising Act (15
9 U.S.C. 1332(2)).

10 (5) CONSTITUENT.—The term “constituent” in
11 relation to cigarettes means any element of main-
12 stream or sidestream smoke.

13 (6) DISTRIBUTOR.—The term “distributor” as
14 regards a tobacco product means any person who
15 furthers the distribution of cigarette or smokeless to-
16 bacco, whether domestic or imported, at any point
17 from the original place of manufacture to the person
18 who sells or distributes the product to individuals for
19 personal consumption. Common carriers are not con-
20 sidered distributors for purposes of this Act.

21 (7) INGREDIENT.—The term “ingredient” in
22 relation to cigarettes or smokeless tobacco products
23 means any substance, chemical, or compound (other
24 than tobacco, water, or reconstituted tobacco sheet
25 made wholly from tobacco) added, or specified for

1 addition, by the manufacturer to the tobacco, paper,
2 or filter of a cigarette, or to the tobacco of a smoke-
3 less tobacco product, including flavorants, processing
4 aids, casing sauces, preservatives, and combustion
5 modifiers.

6 (8) MANUFACTURER.—The term “manufac-
7 turer” means any person who manufactures tobacco
8 products intended to be sold in the United States.
9 The term “manufacturer” shall include an importer
10 or other first purchaser for resale in the United
11 States of tobacco products manufactured outside of
12 the United States or tobacco products manufactured
13 in the United States but not intended for sale in the
14 United States.

15 (9) NICOTINE.—The term “nicotine” means the
16 chemical substance named 3-(1-Methyl-2-
17 pyrrolidinyl) pyridine or C[10]H[14]N[2], including
18 any salt or complex of nicotine.

19 (10) PACKAGE.—The term “package” means a
20 pack, box, carton, or container of any kind or, if no
21 other container, any wrapping (including cello-
22 phane), in which cigarettes or smokeless tobacco are
23 offered for sale, sold, or otherwise distributed to con-
24 sumers.

1 (11) RETAILER.—The term “retailer” means
2 any person who sells cigarettes or smokeless tobacco
3 to individuals for personal consumption, or who op-
4 erates a facility where self-service displays of tobacco
5 products are permitted.

6 (12) SECRETARY.—Except where the context
7 otherwise requires, the term “Secretary” means the
8 Secretary of Health and Human Services.

9 (13) SMOKELESS TOBACCO.—The term “smoke-
10 less tobacco” means any product that consists of
11 cut, ground, powdered, or leaf tobacco and that is
12 intended to be placed in the oral or nasal cavity.

13 **SEC. 4. AMENDMENT OF FEDERAL FOOD, DRUG, AND COS-**
14 **METIC ACT OF 1938.**

15 (a) DEFINITION.—Section 201 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by
17 adding at the end the following:

18 “(kk) The term ‘tobacco product’ means any
19 product made or derived from tobacco that is in-
20 tended for human consumption, including any com-
21 ponent, part, or accessory of a tobacco product (ex-
22 cept for raw materials other than tobacco used in
23 manufacturing a component, part, or accessory of a
24 tobacco product).

1 “(ll) The definitions contained in section 3 of
2 the National Youth Smoking Reduction Act shall
3 apply with respect to chapter IX.”.

4 (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—
5 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 301 et seq.) is amended—

7 (1) by redesignating chapter IX as chapter X;

8 (2) by redesignating sections 901 through 907
9 as sections 1001 through 1007; and

10 (3) by inserting after section 803 the following:

11 **“CHAPTER IX—TOBACCO**
12 **PRODUCTS**

13 **“SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.**

14 “(a) IN GENERAL.—Tobacco products shall be regu-
15 lated by the Secretary under this chapter and shall not
16 be subject to the provisions of chapter V, unless—

17 “(1) such products are intended for use in the
18 diagnosis, cure, mitigation, treatment, or prevention
19 of disease (within the meaning of section
20 201(g)(1)(B) or section 201(h)(2)); or

21 “(2) a health claim is made for such products
22 under section 201(g)(1)(C) or 201(h)(3), unless the
23 product is a reduced risk product pursuant to sec-
24 tion 912.

1 “(b) APPLICABILITY.—This chapter shall apply to all
2 tobacco products subject to the provisions of part 897 of
3 title 21, Code of Federal Regulations, and to any other
4 tobacco products that the Secretary by regulation deems
5 to be subject to this chapter.

6 “(c) SCOPE.—

7 “(1) Nothing in this chapter shall be construed
8 to affect the Secretary’s authority over, or the regu-
9 lation of, products under this Act that are not to-
10 bacco products under chapter V of the Federal
11 Food, Drug and Cosmetic Act or any other chapter
12 of that Act.

13 “(2) The provisions of this chapter shall not
14 apply to tobacco leaf that is not in the possession of
15 the manufacturer, or to the producers of tobacco
16 leaf, including tobacco growers, tobacco warehouses,
17 and tobacco grower cooperatives, nor shall any em-
18 ployee of the Food and Drug Administration have
19 any authority whatsoever to enter onto a farm
20 owned by a producer of tobacco leaf without the
21 written consent of such producer. Notwithstanding
22 any other provision of this subparagraph, if a pro-
23 ducer of tobacco leaf is also a tobacco product man-
24 ufacturer or controlled by a tobacco product manu-
25 facturer, the producer shall be subject to this chap-

1 ter in the producer's capacity as a manufacturer.
2 Nothing in this chapter shall be construed to grant
3 the Secretary authority to promulgate regulations on
4 any matter that involves the production of tobacco
5 leaf or a producer thereof, other than activities by
6 a manufacturer affecting production. For purposes
7 of the preceding sentence, the term 'controlled by'
8 means a member of the same controlled group of
9 corporations as that term is used in section 52(a)
10 of the Internal Revenue Code of 1986, or under
11 common control within the meaning of the regula-
12 tions promulgated under section 52(b) of such Code.

13 **“SEC. 902. ADULTERATED TOBACCO PRODUCTS.**

14 “A tobacco product shall be deemed to be adulterated
15 if—

16 “(1) it consists in whole or in part of any filthy,
17 putrid, or decomposed substance, or is otherwise
18 contaminated by any poisonous or deleterious sub-
19 stance that may render the product more injurious
20 to health;

21 “(2) it has been prepared, packed, or held
22 under insanitary conditions whereby it may have
23 been contaminated with filth, or whereby it may
24 have been rendered more injurious to health;

1 “(3) its container is composed, in whole or in
2 part, of any poisonous or deleterious substance
3 which may render the contents more injurious to
4 health;

5 “(4) it is, or purports to be or is represented
6 as, a tobacco product which is subject to a perform-
7 ance standard established under section 907 unless
8 such tobacco product is in all respects in conformity
9 with such standard;

10 “(5) it is required by section 910(a) to have
11 premarket approval, is not exempt under section
12 906(f), and does not have an approved application in
13 effect;

14 “(6) the methods used in, or the facilities or
15 controls used for, its manufacture, packing or stor-
16 age are not in conformity with applicable require-
17 ments under section 906(e)(1) or an applicable con-
18 dition prescribed by an order under section
19 906(e)(2); or

20 “(7) it is a tobacco product for which an ex-
21 emption has been granted under section 906(f) for
22 investigational use and the person who was granted
23 such exemption or any investigator who uses such
24 tobacco product under such exemption fails to com-

1 ply with a requirement prescribed by or under such
2 section.

3 **“SEC. 903. MISBRANDED TOBACCO PRODUCTS.**

4 “(a) IN GENERAL.—A tobacco product shall be
5 deemed to be misbranded—

6 “(1) if its labeling is false or misleading in any
7 particular;

8 “(2) if in package form unless it bears a label
9 containing—

10 “(A) the name and place of business of the
11 tobacco product manufacturer, packer, or dis-
12 tributor; and

13 “(B) an accurate statement of the quantity
14 of the contents in terms of weight, measure, or
15 numerical count,

16 except that under subparagraph (B) of this para-
17 graph reasonable variations shall be permitted, and
18 exemptions as to small packages shall be established,
19 by regulations prescribed by the Secretary;

20 “(3) if any word, statement, or other informa-
21 tion required by or under authority of this chapter
22 to appear on the label or labeling is not prominently
23 placed thereon with such conspicuousness (as com-
24 pared with other words, statements or designs in the
25 labeling) and in such terms as to render it likely to

1 be read and understood by the ordinary individual
2 under customary conditions of purchase and use;

3 “(4) if it has an established name, unless its
4 label bears, to the exclusion of any other nonpropri-
5 etary name, its established name prominently print-
6 ed in type as required by the Secretary by regula-
7 tion;

8 “(5) if the Secretary has issued regulations re-
9 quiring that its labeling bear adequate directions for
10 use, or adequate warnings against use by children,
11 that are necessary for the protection of users unless
12 its labeling conforms in all respects to such regula-
13 tions;

14 “(6) if it was manufactured, prepared, propa-
15 gated, compounded, or processed in any State in an
16 establishment not duly registered under section
17 905(b), if it was not included in a list required by
18 section 905(i), if a notice or other information re-
19 specting it was not provided as required by such sec-
20 tion or section 905(j), or if it does not bear such
21 symbols from the uniform system for identification
22 of tobacco products prescribed under section 905(e)
23 as the Secretary by regulation requires;

24 “(7) if, in the case of any tobacco product dis-
25 tributed or offered for sale in any State—

1 “(A) its advertising is false or misleading
2 in any particular; or

3 “(B) it is sold, distributed, advertised, or
4 promoted in violation of section 915 or regula-
5 tions prescribed under section 906(d);

6 “(8) unless, in the case of any tobacco product
7 distributed or offered for sale in any State, the man-
8 ufacturer, packer, or distributor thereof includes in
9 all advertisements and other descriptive printed mat-
10 ter issued or caused to be issued by the manufac-
11 turer, packer, or distributor with respect to that to-
12 bacco product—

13 “(A) a true statement of the tobacco prod-
14 uct’s established name as defined in paragraph
15 (4) of this subsection, printed prominently; and

16 “(B) a brief statement of—

17 “(i) the uses of the tobacco product
18 and relevant warnings, precautions, side
19 effects, and contraindications; and

20 “(ii) in the case of specific tobacco
21 products made subject to a finding by the
22 Secretary after notice and opportunity for
23 comment that such action is necessary to
24 protect the public health, a full description
25 of the components of such tobacco product

1 or the formula showing quantitatively each
2 ingredient of such tobacco product to the
3 extent required in regulations which shall
4 be issued by the Secretary after an oppor-
5 tunity for a hearing;

6 “(9) unless, in the case of any tobacco product
7 distributed or offered for sale in any State, the man-
8 ufacturer, packer, or distributor thereof includes in
9 all advertisements the information required by sec-
10 tion 916(c);

11 “(10) if it is a tobacco product subject to a per-
12 formance standard established under section 907,
13 unless it bears such labeling as may be prescribed in
14 such performance standard; or

15 “(11) if there was a failure or refusal—

16 “(A) to comply with any requirement pre-
17 scribed under section 904 or 908; or

18 “(B) to furnish any material or informa-
19 tion required by or under section 909.

20 “(b) PRIOR APPROVAL OF STATEMENTS ON
21 LABEL.—The Secretary may, by regulation, require prior
22 approval of statements made on the label of a tobacco
23 product. No regulation issued under this subsection may
24 require prior approval by the Secretary of the content of
25 any advertisement and no advertisement of a tobacco

1 product, published after the date of enactment of this Act
2 shall, with respect to the matters specified in this section
3 or covered by regulations issued hereunder, be subject to
4 the provisions of sections 12 through 15 of the Federal
5 Trade Commission Act (15 U.S.C. 52 through 55). This
6 subsection does not apply to any printed matter which the
7 Secretary determines to be labeling as defined in section
8 201(m).

9 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**
10 **SECRETARY.**

11 “(a) REQUIREMENT.—Not later than 6 months after
12 the date of enactment of this Act, each tobacco product
13 manufacturer or importer of tobacco products, or agents
14 thereof, shall submit to the Secretary the following infor-
15 mation:

16 “(1) A listing of all tobacco ingredients, sub-
17 stances and compounds that are, on such date,
18 added by the manufacturer to the tobacco, paper, fil-
19 ter, or other component of each tobacco product by
20 brand and by quantity in each brand and subbrand.

21 “(2) A description of the content, delivery, and
22 form of nicotine in each tobacco product measured
23 in milligrams of nicotine.

24 “(3) All documents (including underlying sci-
25 entific information) relating to research activities,

1 and research findings, conducted, supported, or pos-
2 sessed by the manufacturer (or agents thereof) on
3 the health, behavioral, or physiologic effects of to-
4 bacco products, their constituents, ingredients, and
5 components, and tobacco additives, described in
6 paragraph (1).

7 “(4) All documents (including underlying sci-
8 entific information) relating to research activities,
9 and research findings, conducted, supported, or pos-
10 sessed by the manufacturer (or agents thereof) that
11 relate to the issue of whether a reduction in risk to
12 health from tobacco products can occur upon the
13 employment of technology available or known to the
14 manufacturer.

15 “(5) All documents (including underlying sci-
16 entific information) relating to marketing research
17 involving the use of tobacco products.

18 An importer of a tobacco product not manufactured in the
19 United States shall supply the information required of a
20 tobacco product manufacturer under this subsection.

21 “(b) ANNUAL SUBMISSION.—A tobacco product man-
22 ufacturer or importer that is required to submit informa-
23 tion under subsection (a) shall update such information
24 on an annual basis under a schedule determined by the
25 Secretary.

1 “(c) TIME FOR SUBMISSION.—

2 “(1) NEW PRODUCTS.—At least 90 days prior
3 to the delivery for introduction into interstate com-
4 merce of a tobacco product not on the market on the
5 date of enactment of this chapter, the manufacturer
6 of such product shall provide the information re-
7 quired under subsection (a) and such product shall
8 be subject to the annual submission under sub-
9 section (b).

10 “(2) MODIFICATION OF EXISTING PRODUCTS.—

11 If at any time a tobacco product manufacturer adds
12 to its tobacco products a new tobacco additive, in-
13 creases or decreases the quantity of an existing to-
14 bacco additive or the nicotine content, delivery, or
15 form, or eliminates a tobacco additive from any to-
16 bacco product, the manufacturer shall within 60
17 days of such action so advise the Secretary in writ-
18 ing and reference such modification in submissions
19 made under subsection (b).

20 **“SEC. 905. ANNUAL REGISTRATION.**

21 “(a) DEFINITIONS.—As used in this section—

22 “(1) consistent with the provisions of section
23 901(c)(2), the term ‘manufacture, preparation,
24 compounding, or processing’ shall include repack-
25 aging or otherwise changing the container, wrapper,

1 or labeling of any tobacco product package in fur-
2 therance of the distribution of the tobacco product
3 from the original place of manufacture to the person
4 who makes final delivery or sale to the ultimate con-
5 sumer or user; and

6 “(2) the term ‘name’ shall include in the case
7 of a partnership the name of each partner and, in
8 the case of a corporation, the name of each cor-
9 porate officer and director, and the State of incorpo-
10 ration.

11 “(b) REGISTRATION BY OWNERS AND OPERATORS.—
12 On or before December 31 of each year every person who
13 owns or operates any establishment in any State engaged
14 in the manufacture, preparation, compounding, or proc-
15 essing of a tobacco product or tobacco products shall reg-
16 ister with the Secretary the name, places of business, and
17 all such establishments of that person.

18 “(c) REGISTRATION OF NEW OWNERS AND OPERA-
19 TORS.—Every person upon first engaging in the manufac-
20 ture, preparation, compounding, or processing of a tobacco
21 product or tobacco products in any establishment owned
22 or operated in any State by that person shall immediately
23 register with the Secretary that person’s name, place of
24 business, and such establishment.

1 “(d) REGISTRATION OF ADDED ESTABLISHMENTS.—
2 Every person required to register under subsection (b) or
3 (c) shall immediately register with the Secretary any addi-
4 tional establishment which that person owns or operates
5 in any State and in which that person begins the manufac-
6 ture, preparation, compounding, or processing of a tobacco
7 product or tobacco products.

8 “(e) UNIFORM PRODUCT IDENTIFICATION SYS-
9 TEM.—The Secretary may by regulation prescribe a uni-
10 form system for the identification of tobacco products and
11 may require that persons who are required to list such
12 tobacco products under subsection (i) of this section shall
13 list such tobacco products in accordance with such system.

14 “(f) PUBLIC ACCESS TO REGISTRATION INFORMA-
15 TION.—The Secretary shall make available for inspection,
16 to any person so requesting, any registration filed under
17 this section.

18 “(g) BIENNIAL INSPECTION OF REGISTERED ESTAB-
19 LISHMENTS.—Every establishment in any State registered
20 with the Secretary under this section shall be subject to
21 inspection under section 704, and every such establish-
22 ment engaged in the manufacture, compounding, or proc-
23 essing of a tobacco product or tobacco products shall be
24 so inspected by one or more officers or employees duly
25 designated by the Secretary at least once in the 2-year

1 period beginning with the date of registration of such es-
2 tablishment under this section and at least once in every
3 successive 2-year period thereafter.

4 “(h) FOREIGN ESTABLISHMENTS MAY REGISTER.—
5 Any establishment within any foreign country engaged in
6 the manufacture, preparation, compounding, or processing
7 of a tobacco product or tobacco products, may register
8 under this section under regulations promulgated by the
9 Secretary. Such regulations shall require such establish-
10 ment to provide the information required by subsection (i)
11 of this section and shall include provisions for registration
12 of any such establishment upon condition that adequate
13 and effective means are available, by arrangement with the
14 government of such foreign country or otherwise, to enable
15 the Secretary to determine from time to time whether to-
16 bacco products manufactured, prepared, compounded, or
17 processed in such establishment, if imported or offered for
18 import into the United States, shall be refused admission
19 on any of the grounds set forth in section 801(a).

20 “(i) REGISTRATION INFORMATION.—

21 “(1) PRODUCT LIST.—Every person who reg-
22 isters with the Secretary under subsection (b), (c),
23 or (d) of this section shall, at the time of registra-
24 tion under any such subsection, file with the Sec-
25 retary a list of all tobacco products which are being

1 manufactured, prepared, compounded, or processed
2 by that person for commercial distribution and
3 which has not been included in any list of tobacco
4 products filed by that person with the Secretary
5 under this paragraph or paragraph (2) before such
6 time of registration. Such list shall be prepared in
7 such form and manner as the Secretary may pre-
8 scribe and shall be accompanied by—

9 “(A) in the case of a tobacco product con-
10 tained in the applicable list with respect to
11 which a performance standard has been estab-
12 lished under section 907 or which is subject to
13 section 910, a reference to the authority for the
14 marketing of such tobacco product and a copy
15 of all labeling for such tobacco product;

16 “(B) in the case of any other tobacco prod-
17 uct contained in an applicable list, a copy of all
18 consumer information and other labeling for
19 such tobacco product, a representative sampling
20 of advertisements for such tobacco product,
21 and, upon request made by the Secretary for
22 good cause, a copy of all advertisements for a
23 particular tobacco product; and

24 “(C) if the registrant filing a list has de-
25 termined that a tobacco product contained in

1 such list is not subject to a performance stand-
2 ard established under section 907, a brief state-
3 ment of the basis upon which the registrant
4 made such determination if the Secretary re-
5 quests such a statement with respect to that
6 particular tobacco product.

7 “(2) BIENNIAL REPORT OF ANY CHANGE IN
8 PRODUCT LIST.—Each person who registers with the
9 Secretary under this section shall report to the Sec-
10 retary once during the month of June of each year
11 and once during the month of December of each
12 year the following:

13 “(A) A list of each tobacco product intro-
14 duced by the registrant for commercial distribu-
15 tion which has not been included in any list
16 previously filed by that person with the Sec-
17 retary under this subparagraph or paragraph
18 (1) of this subsection. A list under this sub-
19 paragraph shall list a tobacco product by its es-
20 tablished name and shall be accompanied by the
21 other information required by paragraph (1).

22 “(B) If since the date the registrant last
23 made a report under this paragraph that person
24 has discontinued the manufacture, preparation,
25 compounding, or processing for commercial dis-

1 tribution of a tobacco product included in a list
2 filed under subparagraph (A) or paragraph (1),
3 notice of such discontinuance, the date of such
4 discontinuance, and the identity of its estab-
5 lished name.

6 “(C) If since the date the registrant re-
7 ported under subparagraph (B) a notice of dis-
8 continuance that person has resumed the manu-
9 facture, preparation, compounding, or proc-
10 essing for commercial distribution of the to-
11 bacco product with respect to which such notice
12 of discontinuance was reported, notice of such
13 resumption, the date of such resumption, the
14 identity of such tobacco product by established
15 name, and other information required by para-
16 graph (1), unless the registrant has previously
17 reported such resumption to the Secretary
18 under this subparagraph.

19 “(D) Any material change in any informa-
20 tion previously submitted under this paragraph
21 or paragraph (1).

22 “(j) REPORT PRECEDING INTRODUCTION OF CER-
23 TAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO
24 INTERSTATE COMMERCE.—Each person who is required
25 to register under this section and who proposes to begin

1 the introduction or delivery for introduction into interstate
2 commerce for commercial distribution of a tobacco product
3 intended for human use that was not commercially mar-
4 keted (other than for test marketing) in the United States
5 as of the date of enactment of this Act, as defined by the
6 Secretary by regulation shall, at least 90 days before mak-
7 ing such introduction or delivery, report to the Secretary
8 (in such form and manner as the Secretary shall by regu-
9 lation prescribe)—

10 “(1) the basis for such person’s determination
11 that the tobacco product is substantially equivalent,
12 within the meaning of section 910, to a tobacco
13 product commercially marketed (other than for test
14 marketing) in the United States as of the date of
15 this Act’s enactment, that is in compliance with the
16 requirements of this Act; and

17 “(2) action taken by such person to comply
18 with the requirements under section 907 that are
19 applicable to the tobacco product.

20 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**
21 **OF TOBACCO PRODUCTS.**

22 “(a) IN GENERAL.—Any requirement established by
23 or under section 902, 903, 905, or 909 applicable to a
24 tobacco product shall apply to such tobacco product until
25 the applicability of the requirement to the tobacco product

1 has been changed by action taken under section 907, sec-
2 tion 910, or subsection (d) of this section, and any re-
3 quirement established by or under section 902, 903, 905,
4 or 909 which is inconsistent with a requirement imposed
5 on such tobacco product under section 907, section 910,
6 or subsection (d) of this section shall not apply to such
7 tobacco product.

8 “(b) INFORMATION ON PUBLIC ACCESS AND COM-
9 MENT.—Each notice of proposed rulemaking under section
10 907, 908, 909, or 910, or under this section, any other
11 notice which is published in the Federal Register with re-
12 spect to any other action taken under any such section
13 and which states the reasons for such action, and each
14 publication of findings required to be made in connection
15 with rulemaking under any such section shall set forth—

16 “(1) the manner in which interested persons
17 may examine data and other information on which
18 the notice or findings is based; and

19 “(2) the period within which interested persons
20 may present their comments on the notice or find-
21 ings (including the need thereof) orally or in writing,
22 which period shall be at least 60 days but may not
23 exceed 90 days unless the time is extended by the
24 Secretary by a notice published in the Federal Reg-
25 ister stating good cause therefor.

1 “(c) LIMITED CONFIDENTIALITY OF INFORMA-
2 TION.—Any information reported to or otherwise obtained
3 by the Secretary or the Secretary’s representative under
4 section 904, 905, 907, 908, 909, 910, 912, or 704, or
5 under subsection (e) or (f) of this section, which is exempt
6 from disclosure under subsection (a) of section 552 of title
7 5, United States Code, by reason of subsection (b)(4) of
8 that section shall be considered confidential and shall not
9 be disclosed, except that the information may be disclosed
10 to other officers or employees concerned with carrying out
11 this chapter, or when relevant in any proceeding under
12 this chapter.

13 “(d) RESTRICTIONS.—

14 “(1) The Secretary may by regulation require
15 that a tobacco product be restricted to sale or dis-
16 tribution upon such conditions, including restrictions
17 on the access to, and the advertising and promotion
18 of, the tobacco product, as the Secretary may pre-
19 scribe in such regulation if the Secretary determines
20 that such regulation would be appropriate for the
21 prevention of, or decrease in, the use of tobacco
22 products by children under the age at which tobacco
23 products may be legally purchased. No such condi-
24 tion may require that the sale or distribution of a
25 tobacco product be limited to the written or oral au-

1 thorization of a practitioner licensed by law to pre-
2 scribe medical products.

3 “(2) The label of a tobacco product shall bear
4 such appropriate statements of the restrictions re-
5 quired by a regulation under subsection (a) as the
6 Secretary may in such regulation prescribe.

7 “(3) No restriction under paragraph (1) may
8 prohibit the sale of any tobacco product in face-to-
9 face transactions by a specific category of retail out-
10 lets.

11 “(e) GOOD MANUFACTURING PRACTICE REQUIRE-
12 MENTS.—

13 “(1) METHODS, FACILITIES, AND CONTROLS TO
14 CONFORM.—

15 “(A) The Secretary may, in accordance
16 with subparagraph (B), prescribe regulations
17 requiring that the methods used in, and the fa-
18 cilities and controls used for, the manufacture,
19 pre-production design validation (including a
20 process to assess the performance of a tobacco
21 product), packing and storage of a tobacco
22 product, conform to current good manufac-
23 turing practice for an agricultural product, as
24 prescribed in such regulations, to assure that
25 the public health is protected and that the to-

1 bacco product is in compliance with this chap-
2 ter.

3 “(B) The Secretary shall—

4 “(i) before promulgating any regula-
5 tion under subparagraph (A), afford an ad-
6 visory committee an opportunity to submit
7 recommendations with respect to the regu-
8 lation proposed to be promulgated;

9 “(ii) before promulgating any regula-
10 tion under subparagraph (A), afford oppor-
11 tunity for an oral hearing;

12 “(iii) provide the advisory committee a
13 reasonable time to make its recommenda-
14 tion with respect to proposed regulations
15 under subparagraph (A); and

16 “(iv) in establishing the effective date
17 of a regulation promulgated under this
18 subsection, take into account the dif-
19 ferences in the manner in which the dif-
20 ferent types of tobacco products have his-
21 torically been produced, the financial re-
22 sources of the different tobacco product
23 manufacturers, and the state of their exist-
24 ing manufacturing facilities; and shall pro-
25 vide for a reasonable period of time for

1 such manufacturers to conform to good
2 manufacturing practices.

3 “(2) EXEMPTIONS; VARIANCES.—

4 “(A) Any person subject to any require-
5 ment prescribed under paragraph (1) may peti-
6 tion the Secretary for a permanent or tem-
7 porary exemption or variance from such re-
8 quirement. Such a petition shall be submitted
9 to the Secretary in such form and manner as
10 the Secretary shall prescribe and shall—

11 “(i) in the case of a petition for an ex-
12 emption from a requirement, set forth the
13 basis for the petitioner’s determination
14 that compliance with the requirement is
15 not required to assure that the tobacco
16 product will be in compliance with this
17 chapter;

18 “(ii) in the case of a petition for a
19 variance from a requirement, set forth the
20 methods proposed to be used in, and the
21 facilities and controls proposed to be used
22 for, the manufacture, packing, and storage
23 of the tobacco product in lieu of the meth-
24 ods, facilities, and controls prescribed by
25 the requirement; and

1 “(iii) contain such other information
2 as the Secretary shall prescribe.

3 “(B) The Secretary may refer to an advi-
4 sory committee any petition submitted under
5 subparagraph (A). The advisory committee
6 shall report its recommendations to the Sec-
7 retary with respect to a petition referred to it
8 within 60 days after the date of the petition’s
9 referral. Within 60 days after—

10 “(i) the date the petition was sub-
11 mitted to the Secretary under subpara-
12 graph (A); or

13 “(ii) the day after the petition was re-
14 ferred to an advisory committee,
15 whichever occurs later, the Secretary shall by
16 order either deny the petition or approve it.

17 “(C) The Secretary may approve—

18 “(i) a petition for an exemption for a
19 tobacco product from a requirement if the
20 Secretary determines that compliance with
21 such requirement is not required to assure
22 that the tobacco product will be in compli-
23 ance with this chapter; and

24 “(ii) a petition for a variance for a to-
25 bacco product from a requirement if the

1 Secretary determines that the methods to
2 be used in, and the facilities and controls
3 to be used for, the manufacture, packing,
4 and storage of the tobacco product in lieu
5 of the methods, controls, and facilities pre-
6 scribed by the requirement are sufficient to
7 assure that the tobacco product will be in
8 compliance with this chapter.

9 “(D) An order of the Secretary approving
10 a petition for a variance shall prescribe such
11 conditions respecting the methods used in, and
12 the facilities and controls used for, the manu-
13 facture, packing, and storage of the tobacco
14 product to be granted the variance under the
15 petition as may be necessary to assure that the
16 tobacco product will be in compliance with this
17 chapter.

18 “(E) After the issuance of an order under
19 subparagraph (B) respecting a petition, the pe-
20 titioner shall have an opportunity for an infor-
21 mal hearing on such order.

22 “(f) EXEMPTION FOR INVESTIGATIONAL USE.—The
23 Secretary may exempt tobacco products intended for in-
24 vestigational use from this chapter under such conditions
25 as the Secretary may prescribe by regulation.

1 “(g) RESEARCH AND DEVELOPMENT.—The Sec-
2 retary may enter into contracts for research, testing, and
3 demonstrations respecting tobacco products and may ob-
4 tain tobacco products for research, testing, and dem-
5 onstration purposes without regard to section 3324(a) and
6 (b) of title 31, United States Code, and section 5 of title
7 41, United States Code.

8 **“SEC. 907. PERFORMANCE STANDARDS.**

9 “(a) IN GENERAL.—

10 “(1) FINDING REQUIRED.—The Secretary may
11 adopt performance standards for a tobacco product
12 if the Secretary finds that a performance standard
13 is appropriate for the protection of the public health.
14 This finding shall be determined with respect to the
15 risks and benefits to the population as a whole, in-
16 cluding users and non-users of the tobacco product,
17 and taking into account—

18 “(A) the increased or decreased likelihood
19 that existing users of tobacco products will stop
20 using such products; and

21 “(B) the increased or decreased likelihood
22 that those who do not use tobacco products will
23 start using such products.

1 “(2) CONTENT OF PERFORMANCE STAND-
2 ARDS.—A performance standard established under
3 this section for a tobacco product—

4 “(A) shall include provisions to provide
5 performance that is appropriate for the protec-
6 tion of the public health, including provisions,
7 where appropriate—

8 “(i) for the reduction of nicotine
9 yields of the product;

10 “(ii) for the reduction or elimination
11 of other harmful constituents or harmful
12 components of the product; or

13 “(iii) relating to any other require-
14 ment under (B);

15 “(B) shall, where necessary to be appro-
16 priate for the protection of the public health,
17 include—

18 “(i) provisions respecting the con-
19 struction, components, ingredients, and
20 properties of the tobacco product;

21 “(ii) provisions for the testing (on a
22 sample basis or, if necessary, on an indi-
23 vidual basis) of the tobacco product;

1 “(iii) provisions for the measurement
2 of the performance characteristics of the
3 tobacco product; and

4 “(iv) provisions requiring that the re-
5 sults of each or of certain of the tests of
6 the tobacco product required to be made
7 under clause (ii) show that the tobacco
8 product is in conformity with the portions
9 of the standard for which the test or tests
10 were required; and

11 “(C) shall not render the tobacco product
12 unacceptable for adult consumption.

13 “(3) PERIODIC REEVALUATION OF PERFORM-
14 ANCE STANDARDS.—The Secretary shall provide for
15 periodic evaluation of performance standards estab-
16 lished under this section to determine whether such
17 standards should be changed to reflect new medical,
18 scientific, or other technological data. The Secretary
19 may provide for testing under paragraph (2) by any
20 person.

21 “(4) INVOLVEMENT OF OTHER AGENCIES; IN-
22 FORMED PERSONS.—In carrying out duties under
23 this section, the Secretary shall, to the maximum ex-
24 tent practicable—

1 “(A) use personnel, facilities, and other
2 technical support available in other Federal
3 agencies;

4 “(B) consult with other Federal agencies
5 concerned with standard-setting and other na-
6 tionally or internationally recognized standard-
7 setting entities; and

8 “(C) invite appropriate participation,
9 through joint or other conferences, workshops,
10 or other means, by informed persons represent-
11 ative of scientific, professional, industry, or con-
12 sumer organizations who in the Secretary’s
13 judgment can make a significant contribution.

14 “(b) ESTABLISHMENT OF STANDARDS.—

15 “(1) NOTICE.—

16 “(A) The Secretary shall publish in the
17 Federal Register a notice of proposed rule-
18 making for the establishment, amendment, or
19 revocation of any performance standard for a
20 tobacco product.

21 “(B) A notice of proposed rulemaking for
22 the establishment or amendment of a perform-
23 ance standard for a tobacco product shall—

24 “(i) set forth a finding with sup-
25 porting justification that the performance

1 standard is appropriate for the protection
2 of the public health;

3 “(ii) set forth proposed findings with
4 respect to the risk of illness or injury that
5 the performance standard is intended to
6 reduce or eliminate; and

7 “(iii) invite interested persons to sub-
8 mit an existing performance standard for
9 the tobacco product, including a draft or
10 proposed performance standard, for consid-
11 eration by the Secretary.

12 “(C) A notice of proposed rulemaking for
13 the revocation of a performance standard shall
14 set forth a finding with supporting justification
15 that the performance standard is no longer nec-
16 essary to be appropriate for the protection of
17 the public health.

18 “(D) The Secretary shall consider all infor-
19 mation submitted in connection with a proposed
20 standard, including information concerning the
21 countervailing effects of the performance stand-
22 ard on the health of adolescent tobacco users,
23 adult tobacco users, or non-tobacco users, such
24 as the creation of a significant demand for con-
25 traband or other tobacco products that do not

1 meet the requirements of this chapter and the
2 significance of such demand, and shall issue the
3 standard if the Secretary determines that the
4 standard would be appropriate for the protec-
5 tion of the public health.

6 “(E) The Secretary shall provide for a
7 comment period of not less than 60 days.

8 “(2) PROMULGATION.—

9 “(A) After the expiration of the period for
10 comment on a notice of proposed rulemaking
11 published under paragraph (1) respecting a per-
12 formance standard and after consideration of
13 such comments and any report from an advi-
14 sory committee, the Secretary shall—

15 “(i) promulgate a regulation estab-
16 lishing a performance standard and pub-
17 lish in the Federal Register findings on the
18 matters referred to in paragraph (1); or

19 “(ii) publish a notice terminating the
20 proceeding for the development of the
21 standard together with the reasons for
22 such termination.

23 “(B) A regulation establishing a perform-
24 ance standard shall set forth the date or dates
25 upon which the standard shall take effect, but

1 no such regulation may take effect before one
2 year after the date of its publication unless the
3 Secretary determines that an earlier effective
4 date is necessary for the protection of the pub-
5 lic health. Such date or dates shall be estab-
6 lished so as to minimize, consistent with the
7 public health, economic loss to, and disruption
8 or dislocation of, domestic and international
9 trade.

10 “(3) POWER RESERVED TO CONGRESS.—Be-
11 cause of the importance of any decision to issue a
12 regulation establishing a performance standard—

13 “(A) eliminating all cigarettes, all smoke-
14 less tobacco products, or any similar class of to-
15 bacco products, or

16 “(B) requiring the reduction of nicotine
17 yields of a tobacco product to zero,

18 Congress expressly reserves to itself the power to
19 make such a decision.

20 “(4) AMENDMENT; REVOCATION.—

21 “(A) The Secretary, upon the Secretary’s
22 own initiative or upon petition of an interested
23 person may by a regulation, promulgated in ac-
24 cordance with the requirements of paragraphs

1 (1) and (2)(B) of this subsection, amend or re-
2 voke a performance standard.

3 “(B) The Secretary may declare a pro-
4 posed amendment of a performance standard to
5 be effective on and after its publication in the
6 Federal Register and until the effective date of
7 any final action taken on such amendment if
8 the Secretary determines that making it so ef-
9 fective is in the public interest.

10 “(5) REFERENCE TO ADVISORY COMMITTEE.—

11 The Secretary—

12 “(A) may, on the Secretary’s own initia-
13 tive, refer a proposed regulation for the estab-
14 lishment, amendment, or revocation of a per-
15 formance standard; or

16 “(B) shall, upon the request of an inter-
17 ested person which demonstrates good cause for
18 referral and which is made before the expiration
19 of the period for submission of comments on
20 such proposed regulation,

21 refer such proposed regulation to an advisory com-
22 mittee, for a report and recommendation with re-
23 spect to any matter involved in the proposed regula-
24 tion which requires the exercise of scientific judg-
25 ment. If a proposed regulation is referred under this

1 subparagraph to the advisory committee, the Sec-
2 retary shall provide the advisory committee with the
3 data and information on which such proposed regu-
4 lation is based. The advisory committee shall, within
5 60 days after the referral of a proposed regulation
6 and after independent study of the data and infor-
7 mation furnished to it by the Secretary and other
8 data and information before it, submit to the Sec-
9 retary a report and recommendation respecting such
10 regulation, together with all underlying data and in-
11 formation and a statement of the reason or basis for
12 the recommendation. A copy of such report and rec-
13 ommendation shall be made public by the Secretary.

14 **“SEC. 908. NOTIFICATION AND OTHER REMEDIES.**

15 “(a) NOTIFICATION.—If the Secretary determines
16 that—

17 “(1) a tobacco product which is introduced or
18 delivered for introduction into interstate commerce
19 for commercial distribution presents a risk of sub-
20 stantial harm to the public health exceeding the
21 risks posed by tobacco products marketed before the
22 date of enactment of this Act; and

23 “(2) notification under this subsection is nec-
24 essary to eliminate the unreasonable risk of such
25 harm and no more practicable means is available

1 under the provisions of this chapter (other than this
2 section) to eliminate such risk,
3 the Secretary may issue such order as may be necessary
4 to assure that adequate notification is provided in an ap-
5 propriate form, by the persons and means best suited
6 under the circumstances involved, to all persons who
7 should properly receive such notification in order to elimi-
8 nate such risk. The Secretary may order notification by
9 any appropriate means, including public service announce-
10 ments. Before issuing an order under this subsection, the
11 Secretary shall consult with the persons who are to give
12 notice under the order.

13 “(b) NO EXEMPTION FROM OTHER LIABILITY.—
14 Compliance with an order issued under this section shall
15 not relieve any person from liability under Federal or
16 State law.

17 “(c) RECALL AUTHORITY.—

18 “(1) IN GENERAL.—If the Secretary finds that
19 there is a reasonable probability that a tobacco prod-
20 uct contains a manufacturing or other defect not or-
21 dinarily contained in tobacco products on the market
22 that would cause serious, adverse health con-
23 sequences or death, the Secretary shall issue an
24 order requiring the appropriate person (including
25 the manufacturers, importers, distributors, or retail-

1 ers of the tobacco product) to immediately cease dis-
2 tribution of such tobacco product. The order shall
3 provide the person subject to the order with an op-
4 portunity for an informal hearing, to be held not
5 later than 10 days after the date of the issuance of
6 the order, on the actions required by the order and
7 on whether the order should be amended to require
8 a recall of such tobacco product. If, after providing
9 an opportunity for such a hearing, the Secretary de-
10 termines that inadequate grounds exist to support
11 the actions required by the order, the Secretary shall
12 vacate the order.

13 “(2) AMENDMENT OF ORDER TO REQUIRE RE-
14 CALL.—

15 “(A) If, after providing an opportunity for
16 an informal hearing under paragraph (1), the
17 Secretary determines that the order should be
18 amended to include a recall of the tobacco prod-
19 uct with respect to which the order was issued,
20 the Secretary shall, except as provided in sub-
21 paragraph (B), amend the order to require a
22 recall. The Secretary shall specify a timetable in
23 which the tobacco product recall will occur and
24 shall require periodic reports to the Secretary
25 describing the progress of the recall.

1 “(B) An amended order under subpara-
2 graph (A)—

3 “(i) shall not include recall of a to-
4 bacco product from individuals; and

5 “(ii) shall provide for notice to per-
6 sons subject to the risks associated with
7 the use of such tobacco product.

8 In providing the notice required by clause (ii),
9 the Secretary may use the assistance of retail-
10 ers and other persons who distributed such to-
11 bacco product. If a significant number of such
12 persons cannot be identified, the Secretary shall
13 notify such persons under section 705(b).

14 “(3) REMEDY NOT EXCLUSIVE.—The remedy
15 provided by this subsection shall be in addition to
16 remedies provided by subsection (a) of this section.

17 **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**
18 **UCTS.**

19 “(a) IN GENERAL.—Every person who is a tobacco
20 product manufacturer or importer of a tobacco product
21 shall establish and maintain such records, make such re-
22 ports, and provide such information, as the Secretary may
23 by regulation reasonably require to assure that such to-
24 bacco product is not adulterated or misbranded and to

1 otherwise protect public health. Regulations prescribed
2 under the preceding sentence—

3 “(1) may require a tobacco product manufac-
4 turer or importer to report to the Secretary when-
5 ever the manufacturer or importer receives or other-
6 wise becomes aware of information that reasonably
7 suggests that one of its marketed tobacco products
8 may have caused or contributed to a serious unex-
9 pected adverse experience associated with the use of
10 the product or any significant increase in the fre-
11 quency of a serious, expected adverse product experi-
12 ence;

13 “(2) shall require reporting of other significant
14 adverse tobacco product experiences as determined
15 by the Secretary to be necessary to be reported;

16 “(3) shall not impose requirements unduly bur-
17 densome to a tobacco product manufacturer or im-
18 porter, taking into account the cost of complying
19 with such requirements and the need for the protec-
20 tion of the public health and the implementation of
21 this chapter;

22 “(4) when prescribing the procedure for making
23 requests for reports or information, shall require
24 that each request made under such regulations for
25 submission of a report or information to the Sec-

1 retary state the reason or purpose for such request
2 and identify to the fullest extent practicable such re-
3 port or information;

4 “(5) when requiring submission of a report or
5 information to the Secretary, shall state the reason
6 or purpose for the submission of such report or in-
7 formation and identify to the fullest extent prac-
8 ticable such report or information; and

9 “(6) may not require that the identity of any
10 patient or user be disclosed in records, reports, or
11 information required under this subsection unless re-
12 quired for the medical welfare of an individual, to
13 determine risks to public health of a tobacco prod-
14 uct, or to verify a record, report, or information sub-
15 mitted under this chapter.

16 In prescribing regulations under this subsection, the Sec-
17 retary shall have due regard for the professional ethics of
18 the medical profession and the interests of patients. The
19 prohibitions of paragraph (6) of this subsection continue
20 to apply to records, reports, and information concerning
21 any individual who has been a patient, irrespective of
22 whether or when he ceases to be a patient.

23 “(b) REPORTS OF REMOVALS AND CORRECTIONS.—

24 (1) Except as provided in paragraph (3), the
25 Secretary shall by regulation require a tobacco prod-

1 uct manufacturer or importer of a tobacco product
2 to report promptly to the Secretary any corrective
3 action taken or removal from the market of a to-
4 bacco product undertaken by such manufacturer or
5 importer if the removal or correction was
6 undertaken—

7 “(A) to reduce a risk to health posed by
8 the tobacco product; or

9 “(B) to remedy a violation of this chapter
10 caused by the tobacco product which may
11 present a risk to health.

12 A tobacco product manufacturer or importer of a tobacco
13 product who undertakes a corrective action or removal
14 from the market of a tobacco product which is not re-
15 quired to be reported under this subsection shall keep a
16 record of such correction or removal.

17 “(2) No report of the corrective action or re-
18 moval of a tobacco product may be required under
19 paragraph (1) if a report of the corrective action or
20 removal is required and has been submitted under
21 subsection (a) of this section.

22 **“SEC. 910. PREMARKET REVIEW OF CERTAIN TOBACCO**
23 **PRODUCTS.**

24 “(a) IN GENERAL.—

1 “(1) PREMARKET APPROVAL REQUIRED.—Ap-
2 proval under this section of an application for pre-
3 market approval for any tobacco product, other than
4 a reduced risk product under section 912, that is not
5 commercially marketed (other than for test mar-
6 keting) in the United States as of the date of this
7 Act’s enactment, is required unless the manufacturer
8 has submitted a report under section 905(j), and the
9 Secretary has not suspended the distribution of such
10 product under this paragraph. Within 90 days of the
11 submission of a report under section 905(j), the Sec-
12 retary may by order suspend the distribution of the
13 tobacco product that is the subject of that report if
14 the Secretary determines that there is a reasonable
15 likelihood that the tobacco product is not substan-
16 tially equivalent to a tobacco product commercially
17 marketed (other than for test marketing) in the
18 United States as of the date of this Act’s enactment,
19 that is in compliance with the requirements of this
20 Act. If the Secretary fails to issue an order within
21 this 90-day period, then the tobacco product that is
22 the subject of that report shall be deemed to be sub-
23 stantially equivalent to a predicate tobacco product.
24 The issuance of an order under this paragraph shall
25 constitute final agency action for purposes of section

1 702 of title 5, the United States Code; provided,
2 that the Secretary may rescind or modify an order
3 issued under this paragraph at any time.

4 “(2) SUBSTANTIALLY EQUIVALENT DEFINED.—

5 “(A) For purposes of this section and sec-
6 tion 905(j), the term ‘substantially equivalent’
7 or ‘substantial equivalence’ mean, with respect
8 to the tobacco product being compared to the
9 predicate tobacco product, that the Secretary by
10 order has found that the tobacco product—

11 “(i) has the same characteristics as
12 the predicate tobacco product; or

13 “(ii) has different characteristics and
14 the information submitted contains infor-
15 mation, including clinical data if deemed
16 necessary by the Secretary, that dem-
17 onstrates that it is not appropriate to reg-
18 ulate the product under this section be-
19 cause the product could not reasonably be
20 expected to increase the health risks to
21 consumers compared to a conventional to-
22 bacco product that is commercially mar-
23 keted in the United States and that is in
24 compliance with the requirements of this
25 Act.

1 “(B) For purposes of subparagraph (A),
2 the term ‘characteristics’ means the materials,
3 ingredients, design, composition, heating source,
4 or other features of a tobacco product.

5 “(C) A tobacco product may not be found
6 to be substantially equivalent to a predicate to-
7 bacco product that has been removed from the
8 market at the initiative of the Secretary or that
9 has been determined by a judicial order to be
10 misbranded or adulterated.

11 “(3) HEALTH INFORMATION.—

12 “(A) As part of a submission under section
13 905(j) respecting a tobacco product, the person
14 required to file a premarket notification under
15 such section shall provide an adequate summary
16 of any health information related to the tobacco
17 product or state that such information will be
18 made available upon request by any person.

19 “(B) Any summary under subparagraph
20 (A) respecting a tobacco product shall contain
21 detailed information regarding data concerning
22 adverse health effects and shall be made avail-
23 able to the public by the Secretary within 30
24 days of the issuance of a determination that
25 such tobacco product is substantially equivalent

1 to another tobacco product. The communication
2 that such product is a reduced risk product
3 may comply with requirements prescribed by
4 the Secretary relating to such communication,
5 and the Secretary may require prior approval
6 of the communication, in each case in accord-
7 ance with section 912.

8 “(b) APPLICATION.—

9 “(1) CONTENTS.—An application for premarket
10 approval shall contain—

11 “(A) full reports of all information, pub-
12 lished or known to or which should reasonably
13 be known to the applicant, concerning investiga-
14 tions which have been made to show the health
15 risks of such tobacco product and whether such
16 tobacco product presents greater risk than
17 other tobacco products;

18 “(B) a full statement of the components,
19 ingredients, and properties, and of the principle
20 or principles of operation, of such tobacco prod-
21 uct;

22 “(C) a full description of the methods used
23 in, and the facilities and controls used for, the
24 manufacture, processing, and, when relevant,

1 packing and installation of, such tobacco prod-
2 uct;

3 “(D) an identifying reference to any per-
4 formance standard under section 907 which
5 would be applicable to any aspect of such to-
6 bacco product, and either adequate information
7 to show that such aspect of such tobacco prod-
8 uct fully meets such performance standard or
9 adequate information to justify any deviation
10 from such standard;

11 “(E) such samples of such tobacco product
12 and of components thereof as the Secretary
13 may reasonably require;

14 “(F) specimens of the labeling proposed to
15 be used for such tobacco product; and

16 “(G) such other information relevant to
17 the subject matter of the application as the Sec-
18 retary may require.

19 “(2) REFERENCE TO ADVISORY COMMITTEE.—
20 Upon receipt of an application meeting the require-
21 ments set forth in paragraph (1), the Secretary—

22 “(A) may, on the Secretary’s own initia-
23 tive; or

24 “(B) shall, upon the request of an appli-
25 cant,

1 refer such application to an advisory committee and
2 for submission (within such period as the Secretary
3 may establish) of a report and recommendation re-
4 specting approval of the application, together with
5 all underlying data and the reasons or basis for the
6 recommendation.

7 “(c) ACTION ON APPLICATION.—

8 “(1) DEADLINE.—

9 “(A) As promptly as possible, but in no
10 event later than 180 days after the receipt of
11 an application under subsection (b) of this sec-
12 tion, the Secretary, after considering the report
13 and recommendation submitted under para-
14 graph (2) of such subsection, shall—

15 “(i) issue an order approving the ap-
16 plication if the Secretary finds that none of
17 the grounds for denying approval specified
18 in paragraph (2) of this subsection applies;
19 or

20 “(ii) deny approval of the application
21 if the Secretary finds (and sets forth the
22 basis for such finding as part of or accom-
23 panying such denial) that one or more
24 grounds for denial specified in paragraph
25 (2) of this subsection apply.

1 “(B) An order approving an application for
2 a tobacco product may require as a condition to
3 such approval that the sale and distribution of
4 the tobacco product be restricted but only to
5 the extent that the sale and distribution of a
6 tobacco product may be restricted under a regu-
7 lation under section 906(d).

8 “(2) DENIAL OF APPROVAL.—The Secretary
9 shall deny approval of an application for a tobacco
10 product if, upon the basis of the information sub-
11 mitted to the Secretary as part of the application
12 and any other information before the Secretary with
13 respect to such tobacco product, the Secretary finds
14 that—

15 “(A) there is a lack of a showing that per-
16 mitting such tobacco product to be marketed
17 would pose no greater risk to the public health
18 than currently marketed tobacco products;

19 “(B) the methods used in, or the facilities
20 or controls used for, the manufacture, proc-
21 essing, or packing of such tobacco product do
22 not conform to the requirements of section
23 906(e);

1 “(C) based on a fair evaluation of all mate-
2 rial facts, the proposed labeling is false or mis-
3 leading in any particular; or

4 “(D) such tobacco product is not shown to
5 conform in all respects to a performance stand-
6 ard in effect under section 907, compliance with
7 which is a condition to approval of the applica-
8 tion, and there is a lack of adequate informa-
9 tion to justify the deviation from such standard.

10 “(3) DENIAL INFORMATION.—Any denial of an
11 application shall, insofar as the Secretary determines
12 to be practicable, be accompanied by a statement in-
13 forming the applicant of the measures required to
14 place such application in approvable form (which
15 measures may include further research by the appli-
16 cant in accordance with one or more protocols pre-
17 scribed by the Secretary).

18 “(4) BASIS FOR ACTION.—

19 “(A) For purposes of paragraph (2)(A),
20 whether permitting a tobacco product to be
21 marketed would be appropriate for the protec-
22 tion of the public health shall, when appro-
23 priate, be determined on the basis of well-con-
24 trolled investigations, which may include one or
25 more clinical investigations by experts qualified

1 by training and experience to evaluate the to-
2 bacco product.

3 “(B) If the Secretary determines that
4 there exists valid scientific evidence (other than
5 evidence derived from investigations described
6 in subparagraph (A)) which is sufficient to
7 evaluate the tobacco product the Secretary may
8 authorize that the determination for purposes
9 of paragraph (2)(A) be made on the basis of
10 such evidence.

11 “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

12 “(1) IN GENERAL.—The Secretary shall, upon
13 obtaining, where appropriate, advice on scientific
14 matters from an advisory committee, and after due
15 notice and opportunity for informal hearing to the
16 holder of an approved application for a tobacco
17 product, issue an order withdrawing approval of the
18 application if the Secretary finds—

19 “(A) that the continued marketing of such
20 tobacco product poses greater risks to the pub-
21 lic health than other available products;

22 “(B) that the application contained or was
23 accompanied by an untrue statement of a mate-
24 rial fact;

25 “(C) that the applicant—

1 “(i) has failed to establish a system
2 for maintaining records, or has repeatedly
3 or deliberately failed to maintain records
4 or to make reports, required by an applica-
5 ble regulation under section 909;

6 “(ii) has refused to permit access to,
7 or copying or verification of, such records
8 as required by section 704; or

9 “(iii) has not complied with the re-
10 quirements of section 905;

11 “(D) on the basis of new information be-
12 fore the Secretary with respect to such tobacco
13 product, evaluated together with the evidence
14 before the Secretary when the application was
15 approved, that the methods used in, or the fa-
16 cilities and controls used for, the manufacture,
17 processing, packing, or installation of such to-
18 bacco product do not conform with the require-
19 ments of section 906(e) and were not brought
20 into conformity with such requirements within a
21 reasonable time after receipt of written notice
22 from the Secretary of nonconformity;

23 “(E) on the basis of new information be-
24 fore the Secretary, evaluated together with the
25 evidence before the Secretary when the applica-

1 tion was approved, that the labeling of such to-
2 bacco product, based on a fair evaluation of all
3 material facts, is false or misleading in any par-
4 ticular and was not corrected within a reason-
5 able time after receipt of written notice from
6 the Secretary of such fact; or

7 “(F) on the basis of new information be-
8 fore the Secretary, evaluated together with the
9 evidence before the Secretary when the applica-
10 tion was approved, that such tobacco product is
11 not shown to conform in all respects to a per-
12 formance standard which is in effect under sec-
13 tion 907, compliance with which was a condi-
14 tion to approval of the application, and that
15 there is a lack of adequate information to jus-
16 tify the deviation from such standard.

17 “(2) APPEAL.—The holder of an application
18 subject to an order issued under paragraph (1) with-
19 drawing approval of the application may, by petition
20 filed on or before the thirtieth day after the date
21 upon which he receives notice of such withdrawal,
22 obtain review thereof in accordance with subsection
23 (e) of this section.

24 “(3) TEMPORARY SUSPENSION.—If, after pro-
25 viding an opportunity for an informal hearing, the

1 Secretary determines there is reasonable probability
2 that the continuation of distribution of a tobacco
3 product under an approved application would cause
4 serious, adverse health consequences or death, that
5 is greater than ordinarily caused by tobacco prod-
6 ucts on the market, the Secretary shall by order
7 temporarily suspend the approval of the application
8 approved under this section. If the Secretary issues
9 such an order, the Secretary shall proceed expedi-
10 tiously under paragraph (1) to withdraw such appli-
11 cation.

12 “(e) SERVICE OF ORDER.—An order issued by the
13 Secretary under this section shall be served—

14 “(1) in person by any officer or employee of the
15 department designated by the Secretary; or

16 “(2) by mailing the order by registered mail or
17 certified mail addressed to the applicant at the ap-
18 plicant’s last known address in the records of the
19 Secretary.

20 **“SEC. 911. JUDICIAL REVIEW.**

21 “(a) IN GENERAL.—Not later than 30 days after—

22 “(1) the promulgation of a regulation under
23 section 907 establishing, amending, or revoking a
24 performance standard for a tobacco product; or

1 “(2) a denial of an application for approval
2 under section 910(c),
3 any person adversely affected by such regulation or order
4 may file a petition with the United States Court of Ap-
5 peals for the District of Columbia or for the circuit where-
6 in such person resides or has his principal place of busi-
7 ness for judicial review of such regulation or order. A copy
8 of the petition shall be transmitted by the clerk of the
9 court to the Secretary or other officer designated by the
10 Secretary for that purpose. The Secretary shall file in the
11 court the record of the proceedings on which the Secretary
12 based the Secretary’s regulation or order and each record
13 or order shall contain a statement of the reasons for its
14 issuance and the basis, on the record, for its issuance. For
15 purposes of this section, the term ‘record’ means all no-
16 tices and other matter published in the Federal Register
17 with respect to the regulation or order reviewed, all infor-
18 mation submitted to the Secretary with respect to such
19 regulation or order, proceedings of any panel or advisory
20 committee with respect to such regulation or order, any
21 hearing held with respect to such regulation or order, and
22 any other information identified by the Secretary, in the
23 administrative proceeding held with respect to such regu-
24 lation or order, as being relevant to such regulation or
25 order.

1 “(b) COURT MAY ORDER SECRETARY TO MAKE AD-
2 DITIONAL FINDINGS.—If the petitioner applies to the
3 court for leave to adduce additional data, views, or argu-
4 ments respecting the regulation or order being reviewed
5 and shows to the satisfaction of the court that such addi-
6 tional data, views, or arguments are material and that
7 there were reasonable grounds for the petitioner’s failure
8 to adduce such data, views, or arguments in the pro-
9 ceedings before the Secretary, the court may order the
10 Secretary to provide additional opportunity for the oral
11 presentation of data, views, or arguments and for written
12 submissions. The Secretary may modify the Secretary’s
13 findings, or make new findings by reason of the additional
14 data, views, or arguments so taken and shall file with the
15 court such modified or new findings, and the Secretary’s
16 recommendation, if any, for the modification or setting
17 aside of the regulation or order being reviewed, with the
18 return of such additional data, views, or arguments.

19 “(c) STANDARD OF REVIEW.—Upon the filing of the
20 petition under subsection (a) of this section for judicial
21 review of a regulation or order, the court shall have juris-
22 diction to review the regulation or order in accordance
23 with chapter 7 of title 5, United States Code, and to grant
24 appropriate relief, including interim relief, as provided in
25 such chapter. A regulation or order described in paragraph

1 (1) or (2) of subsection (a) of this section shall not be
2 affirmed if it is found to be unsupported by substantial
3 evidence on the record taken as a whole.

4 “(d) FINALITY OF JUDGMENT.—The judgment of the
5 court affirming or setting aside, in whole or in part, any
6 regulation or order shall be final, subject to review by the
7 Supreme Court of the United States upon certiorari or
8 certification, as provided in section 1254 of title 28,
9 United States Code.

10 “(e) OTHER REMEDIES.—The remedies provided for
11 in this section shall be in addition to and not in lieu of
12 any other remedies provided by law.

13 “(f) REGULATIONS AND ORDERS MUST RECITE
14 BASIS IN RECORD.—To facilitate judicial review under
15 this section or under any other provision of law of a regu-
16 lation or order issued under section 906, 907, 908, 909,
17 910, or 913, each such regulation or order shall contain
18 a statement of the reasons for its issuance and the basis,
19 in the record of the proceedings held in connection with
20 its issuance, for its issuance.

21 **“SEC. 912. REDUCED RISK TOBACCO PRODUCTS.**

22 “(a) REQUIREMENTS.—

23 “(1) IN GENERAL.—For purposes of this sec-
24 tion, the term ‘reduced risk tobacco product’ means

1 a tobacco product designated by the Secretary under
2 paragraph (2).

3 “(2) DESIGNATION.—

4 “(A) IN GENERAL.—A product may be
5 designated by the Secretary as a reduced risk
6 tobacco product if the Secretary finds that the
7 product is demonstrated to significantly reduce
8 harm to individuals caused by a tobacco prod-
9 uct and is otherwise appropriate to protect pub-
10 lic health, based on an application submitted by
11 the manufacturer of the product (or other re-
12 sponsible person) that—

13 “(i)(I) demonstrates through testing
14 on animals and short-term human testing
15 that use of such product results in inges-
16 tion or inhalation of a substantially lower
17 yield of toxic substances than use of an-
18 other tobacco product in the same or dif-
19 ferent category as the proposed reduced
20 risk product; or

21 “(II) contains scientific evidence
22 showing that use of such product results in
23 a substantially lower potential risk to
24 health in one or more specific respects
25 than use of another tobacco product in the

1 same or different category as the proposed
2 reduced risk product; and

3 “(ii) if required by the Secretary, in-
4 cludes studies of the long-term health ef-
5 fects of the product.

6 If such studies are required, the manufacturer
7 may consult with the Secretary regarding proto-
8 cols for conducting the studies.

9 “(B) BASIS FOR FINDING.—In making the
10 finding under subparagraph (A), the Secretary
11 shall take into account—

12 “(i) the risks and benefits to the pop-
13 ulation as a whole, including both users of
14 tobacco products and non-users of tobacco
15 products;

16 “(ii) the increased or decreased likeli-
17 hood that existing users of tobacco prod-
18 ucts will stop using such products includ-
19 ing reduced risk tobacco products;

20 “(iii) the increased or decreased likeli-
21 hood that those who do not use tobacco
22 products will start to use such products,
23 including reduced risk tobacco products;
24 and

1 “(iv) the risks and benefits to con-
2 sumers from the use of a reduced risk to-
3 bacco product as compared to the use of
4 products approved under chapter V to re-
5 duce exposure to tobacco.

6 “(3) MARKETING REQUIREMENTS.—A tobacco
7 product may be marketed and labeled as a reduced
8 risk tobacco product if it—

9 “(A) has been designated as a reduced risk
10 tobacco product by the Secretary under para-
11 graph (2);

12 “(B) bears a label prescribed by the Sec-
13 retary concerning the product’s contribution to
14 reducing harm to health; and

15 “(C) complies with requirements prescribed
16 by the Secretary relating to marketing and ad-
17 vertising of the product, and other provisions of
18 this chapter as prescribed by the Secretary, al-
19 though in no event shall such requirements pro-
20 hibit the communication that such product is a
21 reduced risk product. The communication that
22 such product is a reduced risk product may
23 comply with requirements prescribed by the
24 Secretary relating to such communication, and

1 the Secretary may require prior approval of the
2 communication.

3 “(b) REVOCATION OF DESIGNATION.—At any time
4 after the date on which a tobacco product is designated
5 as a reduced risk tobacco product under this section the
6 Secretary may, after providing an opportunity for an in-
7 formal hearing, revoke such designation if the Secretary
8 determines, based on information not available at the time
9 of the designation, that—

10 “(1) the finding made under subsection (a)(2)
11 is no longer valid; or

12 “(2) the product is being marketed in violation
13 of subsection (a)(3).

14 “(c) LIMITATION.—A tobacco product that is des-
15 igned as a reduced risk tobacco product that is in com-
16 pliance with subsection (a) shall not be regulated as a
17 drug or device.

18 “(d) DEVELOPMENT OF REDUCED RISK TOBACCO
19 PRODUCT TECHNOLOGY.—A tobacco product manufac-
20 turer shall provide written notice to the Secretary upon
21 the development or acquisition by the manufacturer of any
22 technology that would reduce the risk of a tobacco product
23 to the health of the user for which the manufacturer is
24 not seeking designation as a ‘reduced risk tobacco product’
25 under subsection (a).

1 “(e) POSTMARKET SURVEILLANCE.—

2 “(1) DISCRETIONARY SURVEILLANCE.—The
3 Secretary may require a tobacco product manufac-
4 turer to conduct postmarket surveillance for reduced
5 risk a tobacco product of the manufacturer if the
6 Secretary determines that postmarket surveillance of
7 the tobacco product is necessary to protect the pub-
8 lic health or is necessary to provide information re-
9 garding the health risks and other safety issues in-
10 volving the tobacco product.

11 “(2) SURVEILLANCE APPROVAL.—Each tobacco
12 product manufacturer required to conduct a surveil-
13 lance of a reduced risk tobacco product under para-
14 graph (1) shall, within 30 days after receiving notice
15 that the manufacturer is required to conduct such
16 surveillance, submit, for the approval of the Sec-
17 retary, a protocol for the required surveillance. The
18 Secretary, within 60 days of the receipt of such pro-
19 tocol, shall determine if the principal investigator
20 proposed to be used in the surveillance has sufficient
21 qualifications and experience to conduct such sur-
22 veillance and if such protocol will result in collection
23 of useful data or other information necessary to pro-
24 tect the public health. The Secretary may not ap-
25 prove such a protocol until it has been reviewed by

1 an appropriately qualified scientific and technical re-
2 view committee established by the Secretary.

3 **“SEC. 913. PRESERVATION OF STATE AND LOCAL AUTHOR-**
4 **ITY.**

5 “(a) ADDITIONAL REQUIREMENTS.—

6 “(1) IN GENERAL.—Except as provided in para-
7 graph (2), nothing in this Act shall be construed as
8 prohibiting a State or political subdivision thereof
9 from adopting or enforcing a requirement applicable
10 to a tobacco product that is in addition to, or more
11 stringent than, requirements established under this
12 chapter.

13 “(2) PREEMPTION OF CERTAIN STATE AND
14 LOCAL REQUIREMENTS.—

15 “(A) Except as provided in subparagraph
16 (B), no State or political subdivision of a State
17 may establish or continue in effect with respect
18 to a tobacco product any requirement which is
19 different from, or in addition to, any require-
20 ment applicable under the provisions of this
21 chapter relating to performance standards, pre-
22 market approval, adulteration, misbranding,
23 registration, labeling, good manufacturing
24 standards, or reduced risk products.

1 “(B) Subparagraph (A) does not apply to
2 requirements relating to the sale, use, or dis-
3 tribution of a tobacco product including require-
4 ments related to the access to, and the adver-
5 tising and promotion of, a tobacco product.

6 “(b) **RULE OF CONSTRUCTION REGARDING PRODUCT**
7 **LIABILITY.**—No provision of this chapter relating to a to-
8 bacco product shall be construed to modify or otherwise
9 affect any action or the liability of any person under the
10 product liability law of any State.

11 **“SEC. 914. EQUAL TREATMENT OF RETAIL OUTLETS.**

12 “The Secretary shall issue regulations to require that
13 retail establishments for which the predominant business
14 is the sale of tobacco products comply with any advertising
15 restrictions applicable to retail establishments accessible
16 to individuals under the age of 18.

17 **“SEC. 915. ACCESS AND MARKETING RESTRICTIONS.**

18 “(a) **DEFINITIONS.**—For purposes of this section, the
19 following definitions apply:

20 “(1) **ADULT.**—The term ‘adult’ means any per-
21 son who is older than the minimum age at which it
22 is legal to purchase or possess (whichever minimum
23 age is older) tobacco products.

24 “(2) **ADULT-ONLY FACILITY.**—The term ‘adult-
25 only facility’ means a facility or restricted area

1 (whether open-air or enclosed) where the operator
2 ensures or has a reasonable basis to believe (such as
3 by checking identification as required under state
4 law, or by checking the identification of any person
5 appearing to be under the age of 27) that only
6 adults are present. A facility or restricted area need
7 not be permanently restricted to adults in order to
8 constitute an adult-only facility, provided that the
9 operator ensures or has a reasonable basis to believe
10 that only adults are present during the event or time
11 period in question.

12 “(3) BRAND NAME.—The term ‘brand name’
13 means a brand name (alone or in conjunction with
14 any other word), trademark, logo, symbol, motto,
15 selling message, recognizable pattern of colors, or
16 any other indicia of product identification identical
17 or similar to, or identifiable with, those used for any
18 domestic brand of tobacco products. The term
19 ‘brand name’ shall not include the corporate name
20 of any tobacco product manufacturer that does not
21 after the date of the enactment of this Act sell a
22 brand of tobacco products in the United States that
23 includes such corporate name.

24 “(b) CIGARETTE AND SMOKELESS TOBACCO PROD-
25 UCT REQUIREMENTS.—

1 “(1) MINIMUM SALES AGE.—No retailer may
2 sell a tobacco product to any person younger than
3 18 years of age.

4 “(2) PROOF OF AGE.—

5 “(A) Except as otherwise provided in sub-
6 paragraph (B), each retailer shall verify by
7 means of photographic identification containing
8 the bearer’s date of birth that no person pur-
9 chasing the product is younger than 18 years of
10 age.

11 “(B) No such verification is required for
12 any person over the age of 26.

13 “(3) ENFORCEMENT BY THE STATES.—The
14 Secretary may enter into an agreement with any
15 State which has in effect a State law that is at least
16 as restrictive as this subsection, whereby such State
17 agrees to enforce such State law in a manner rea-
18 sonably designed to prevent its violation and the
19 Secretary provides a grant to such State for the pur-
20 pose of enforcing such State law. No action taken by
21 the Secretary pursuant to this paragraph shall be
22 construed to limit the authority of the Secretary
23 under this subsection.

24 “(4) MAIL ORDER SALES.—After two years
25 from the date of enactment of this Act, the Sec-

1 retary shall transmit to Congress a report describing
2 the extent, if any, to which individuals younger than
3 18 years of age are obtaining tobacco products
4 through the mail.

5 “(c) MINIMUM PACKAGE SIZE REQUIREMENTS.—

6 “(1) No manufacturer, distributor, or retailer
7 may sell or cause to be sold, or distribute or cause
8 to be distributed, any cigarette package that con-
9 tains fewer than 20 cigarettes.

10 “(2) No retailer may break or otherwise open
11 any tobacco product package to sell or distribute in-
12 dividual cigarettes or a number of unpackaged ciga-
13 rettes that is smaller than the quantity in the min-
14 imum cigarette package size provided in paragraph
15 (1), or any quantity of another tobacco product that
16 is smaller than the smallest package distributed by
17 the manufacturer for individual consumer use.

18 “(d) BAN ON YOUTH ACCESS TO FREE SAMPLES.—

19 “(1) No manufacturer, distributor, or retailer
20 may distribute or cause to be distributed any free
21 samples of tobacco products, except in an adult-only
22 facility.

23 “(2) For purposes of this subsection, a ‘free
24 sample’ does not include a tobacco product that is
25 provided to an adult in connection with—

1 “(A) the purchase, exchange or redemption
2 for proof of purchase of any tobacco products
3 (including, but not limited to, a free offer in
4 connection with the purchase of tobacco prod-
5 ucts, such as a ‘two-for-one’ offer), or

6 “(B) the conducting of consumer testing or
7 evaluation of tobacco products with persons who
8 certify that they are adults.

9 “(e) VENDING MACHINES, SELF-SERVICE DISPLAYS,
10 MAIL-ORDER SALES, AND OTHER ‘IMPERSONAL’ MODES
11 OF SALE.—

12 “(1) Except as otherwise provided in paragraph
13 (2), a retailer may sell a tobacco product only in a
14 direct, face-to-face exchange between the retailer and
15 the consumer. Examples of methods of sale that are
16 not permitted include vending machines and self-
17 service displays.

18 “(2) The following methods of sale are per-
19 mitted under this subsection:

20 “(A) Mail-order sales, excluding mail-order
21 redemption of coupons and distribution of free
22 samples through the mail.

23 “(B) Vending machines that are located in
24 an adult-only facility.

1 “(3) For purposes of this section, a ‘self-serv-
2 ice’ display means any display where the customer
3 has access to the tobacco products without the aid
4 of a sales clerk.

5 “(f) PROHIBITION ON YOUTH TARGETING.—No
6 manufacturer, distributor, or retailer may take any action,
7 directly or indirectly, to target youth in the advertising,
8 promotion, or marketing of tobacco products, or take any
9 action the primary purpose of which is to initiate, main-
10 tain, or increase the incidence of youth smoking. For pur-
11 poses of this subsection, the term ‘youth’ means any per-
12 son or persons under 18 years of age.

13 “(g) BAN ON USE OF CARTOONS.—

14 “(1) No manufacturer, distributor, or retailer
15 may use or cause to be used any cartoon in the ad-
16 vertising, promoting, packaging, or labeling of to-
17 bacco products.

18 “(2) For purposes of this subsection, the term
19 ‘cartoon’ means any drawing or other depiction of
20 an object, person, animal, creature, or any similar
21 caricature that satisfies any of the following criteria:

22 “(A) The use of comically exaggerated fea-
23 tures;

1 “(B) The attribution of human character-
2 istics to animals, plants, or other objects, or the
3 similar use of anthropomorphic technique.

4 “(C) The attribution of unnatural or
5 extrahuman abilities, such as imperviousness to
6 pain or injury, X-ray vision, tunneling at very
7 high speeds, or transformation.

8 “(3) The term ‘cartoon’ includes ‘Joe Camel,’
9 but does not include any drawing or other depiction
10 that, on July 1, 1998, was in use in the United
11 States in any manufacturer’s corporate logo or in
12 any manufacturer’s tobacco product packaging.

13 “(h) ELIMINATION OF OUTDOOR ADVERTISING.—

14 “(1) No manufacturer, distributor, or retailer
15 may place or cause to be placed any outdoor adver-
16 tising advertising tobacco products.

17 “(2) For purposes of this subsection, the term
18 ‘outdoor advertising’ means—

19 “(A) billboards;

20 “(B) signs and placards in arenas, sta-
21 diums, shopping malls, and video game arcades
22 (whether any of the foregoing are open air or
23 enclosed); and

24 “(C) any other advertisements placed—

25 “(i) outdoors, or

1 “(ii) on the inside surface of a window
2 facing outward.

3 “(D) The term ‘outdoor advertising’ does
4 not mean—

5 “(i) an advertisement on the outside
6 of a tobacco product manufacturing facil-
7 ity;

8 “(ii) an individual advertisement that
9 does not occupy an area larger than 14
10 square feet (and that neither is placed in
11 such proximity to any other such advertise-
12 ment so as to create a single ‘mosaic’-type
13 advertisement larger than 14 square feet,
14 nor functions solely as a segment of a larg-
15 er advertising unit or series), and that is
16 placed on the outside of any retail estab-
17 lishment that sells tobacco products (other
18 than solely through a vending machine), on
19 the outside (but on the property of) any
20 such establishment, or on the inside sur-
21 face of a window facing outward in any
22 such establishment; or

23 “(iii) an advertisement inside a retail
24 establishment that sells tobacco products
25 (other than solely through a vending ma-

1 chine) that is not placed on the inside sur-
2 face of a window facing outward.

3 “(3) For purposes of this subsection, the term
4 ‘video game arcade’ means an entertainment estab-
5 lishment primarily consisting of video games (other
6 than video games intended primarily for use by per-
7 sons 18 years of age or older) and/or pinball ma-
8 chines.

9 “(i) ELIMINATION OF TRANSIT ADVERTISEMENTS.—

10 “(1) No manufacturer, distributor, or retailer
11 may place or cause to be placed any transit adver-
12 tisements advertising tobacco products.

13 “(2) For purposes of this subsection, the term
14 ‘transit advertisements’ means advertising on or
15 within private or public vehicles and all advertise-
16 ments placed at, on or within any bus stop, taxi
17 stand, transportation waiting area, train station, air-
18 port, or any similar location.

19 “(3) The term ‘transit advertisements’ does not
20 include any advertisement placed in, on, or outside
21 the premises of any retail establishment that sells
22 tobacco products (other than solely through a vend-
23 ing machine), except if such individual
24 advertisement—

1 “(A) occupies an area larger than 14
2 square feet;

3 “(B) is placed in such proximity to any
4 other such advertisement so as to create a sin-
5 gle ‘mosaic’-type advertisement larger than 14
6 square feet; or

7 “(C) functions solely as a segment of a
8 larger advertising unit or series).

9 “(j) BAR ON ADVERTISING IN ANY YOUTH-ORI-
10 ENTED PUBLICATION.—

11 “(1) No manufacturer, distributor, or retailer
12 shall advertise a tobacco product in any youth-ori-
13 ented publication (whether periodic or limited dis-
14 tribution).

15 “(2) For purposes of this subsection, a ‘youth
16 oriented publication’ is a newspaper, magazine, peri-
17 odical, or other publication—

18 “(A) whose readers younger than 18 years
19 of age constitute more than 15 percent of the
20 total readership as measured by competent and
21 reliable survey evidence; or

22 “(B) that is read by 2,000,000 or more
23 persons younger than 18 years of age as meas-
24 ured by competent and reliable survey evidence.

1 “(k) BAN ON TOBACCO PRODUCT BRAND NAME
2 SPONSORSHIPS.—

3 “(1) No manufacturer, distributor, or retailer
4 may sponsor or cause to be sponsored any athletic,
5 musical, artistic, or other social or cultural event, or
6 any entry or team in any event, in the brand name
7 (alone or in conjunction with any other word), logo,
8 symbol, motto, selling message, recognizable color or
9 pattern of colors, or any other indicia of product
10 identification identical or similar to, or identifiable
11 with, those used for any brand of cigarettes or
12 smokeless tobacco.

13 “(2) Nothing in this subsection shall be con-
14 strued to prevent a manufacturer, distributor, or re-
15 tailer from sponsoring or causing to be sponsored
16 any athletic, musical, artistic, or other social or cul-
17 tural event, or team or entry, in the name of the
18 corporation which manufactures the tobacco product,
19 provided that both the corporate name and the cor-
20 poration were registered and in use in the United
21 States prior to January 1, 2001, and that the cor-
22 porate name does not include any brand name (alone
23 or in conjunction with any other word), logo, symbol,
24 motto, selling message, recognizable color or pattern
25 of colors, or any other indicia of product identifica-

1 tion identical or similar to, or identifiable with, those
2 used for any brand of cigarettes or smokeless to-
3 bacco.

4 “(3) This subsection shall not apply to any
5 event sponsored in an adult-only facility.

6 “(1) BAN ON TOBACCO BRAND NAME MERCHAN-
7 DISE.—

8 “(1) No manufacturer may market, distribute,
9 offer, sell, license or cause to be marketed, distrib-
10 uted, offered, sold, or licensed (including, without
11 limitation, by catalogue or direct mail), any apparel
12 or other merchandise (other than tobacco products,
13 items the sole function of which is to advertise to-
14 bacco products, or written or electronic publications)
15 which bears a brand name.

16 “(2) Nothing in this subsection shall—

17 “(A) prohibit the distribution to any man-
18 ufacturer’s employee who is an adult of any
19 item described above that is intended for the
20 personal use of such an employee;

21 “(B) require any manufacturer to retrieve,
22 collect or otherwise recover any item that prior
23 to the enactment of this Act was marketed, dis-
24 tributed, offered, sold, licensed, or caused to be

1 marketed, distributed, offered, sold, or licensed
2 by such manufacturer;

3 “(C) apply to coupons or other items used
4 by adults solely in connection with the purchase
5 of tobacco products; or

6 “(D) apply to apparel or other merchan-
7 dise used within an adult-only facility that is
8 not distributed (by sale or otherwise) to any
9 member of the general public.

10 “(m) BAN ON GIFTS TO UNDERAGE PERSONS BASED
11 ON PROOFS OF PURCHASE.—

12 “(1) No manufacturer, distributor, or retailer
13 may provide or cause to be provided to any person,
14 without sufficient proof that such person is an adult,
15 any item in exchange for the purchase of tobacco
16 products, or the furnishing of credits, proofs-of-pur-
17 chase, or coupons with respect to such a purchase.

18 “(2)(A) For purposes of paragraph (1), a driv-
19 er’s license or other government-issued identification
20 (or legible photocopy thereof), the validity of which
21 is certified by the person to whom the item is pro-
22 vided, shall by itself be deemed to be a sufficient
23 form of proof of age; and

24 “(B) In the case of items provided (or to be re-
25 deemed) at retail establishments, a manufacturer

1 shall be entitled to rely on verification of proof of
2 age by the retailer, where such retailer is required
3 to obtain verification under applicable Federal, State
4 or local law.

5 “(n) BAN ON NON-TOBACCO PRODUCT BRAND
6 NAMES.—

7 “(1) Except as provided in paragraph (2), no
8 manufacturer may, pursuant to any agreement re-
9 quiring the payment of money or other valuable con-
10 sideration, use or cause to be used as a brand name
11 of any tobacco product any nationally recognized or
12 nationally established brand name or trade name of
13 any non-tobacco item or service or any nationally
14 recognized or nationally established sports team, en-
15 tertainment group, or individual celebrity.

16 “(2) Paragraph (1) shall not apply to any to-
17 bacco product brand name in existence as of July 1,
18 1998.

19 “(3) For the purposes of this section, the term
20 ‘other valuable consideration’ shall not include an
21 agreement between two entities who enter into such
22 agreement for the sole purpose of avoiding infringe-
23 ment claims.

24 “(o) LIMITATION ON THIRD PARTY USE OF TO-
25 BACCO BRAND NAMES.—

1 “(1) No manufacturer may license or otherwise
2 expressly authorize any third party to use or adver-
3 tise any brand name in a manner prohibited by this
4 Act if done by such manufacturer itself.

5 “(2) Nothing in this subsection shall require
6 any manufacturer to retrieve, collect, or otherwise
7 recover any item that prior to the enactment of this
8 Act was marketed, distributed, offered, sold, li-
9 censed, or caused to be marketed, distributed, of-
10 fered, sold, or licensed by such manufacturer.

11 “(p) BAR ON PRODUCT PLACEMENT IN CERTAIN
12 MEDIA.—

13 “(1) Except as provided in paragraph (2), no
14 manufacturer may make, or cause to be made, any
15 payment or other consideration to any other person
16 or entity to use, display, make reference to, or use
17 as a prop any tobacco product, tobacco product
18 package, advertisement for a tobacco product, or any
19 other item bearing a brand name in any motion pic-
20 ture, television show, theatrical production or other
21 live performance, live or recorded performance of
22 music, commercial film or video, or video game
23 (‘media’).

24 “(2) Paragraph (1) shall not apply to—

1 “(A) media where the audience or viewers
2 are within an adult-only facility (provided such
3 media are not visible to persons outside such
4 adult-only facility);

5 “(B) media not intended for distribution or
6 display to the public; or

7 “(C) instructional media concerning non-
8 conventional tobacco products or tobacco prod-
9 ucts designated as reduced risk viewed only by
10 or provided only to consumers who are adults.

11 “(q) SEVERABILITY.—If any provision of this section
12 is held invalid, those subsections, and paragraphs which
13 are not so held shall continue to be in effect.

14 “(r) EFFECTIVE DATES.—The provisions of this sec-
15 tion shall take effect on the date that is six months after
16 the date of enactment of this section, except for the provi-
17 sions of subsections (e) and (k), which shall take effect
18 on the date that is one year after the effective date of
19 this section.

20 **“SEC. 916. MANDATORY DISCLOSURES.**

21 “(a) DISCLOSURE OF INGREDIENTS TO THE PUB-
22 LIC.—

23 “(1) Not later than 12 months after the effec-
24 tive date of this section, the Secretary shall promul-
25 gate regulations requiring the disclosure to the pub-

1 lic on a brand-by-brand basis of the common or
2 usual name of each ingredient of a tobacco product
3 in descending order of predominance by weight, ex-
4 cept that spices, flavorings, and colorings may at the
5 manufacturer’s election be designated as spices,
6 flavorings, and colorings without naming each. Any
7 ingredient that has been disclosed to the public pur-
8 suant to any other law or regulation with respect to
9 a particular brand may be required to be disclosed
10 for such brand pursuant to this subsection.

11 “(2) The regulations required by this subsection
12 shall provide that incidental additives that are
13 present in a tobacco product at insignificant levels
14 and that do not have any technical or functional ef-
15 fect in the finished tobacco product shall be exempt
16 from disclosure.

17 “(3) The requirement of this subsection to dis-
18 close ingredients in descending order of predomi-
19 nance shall not apply to ingredients in amounts of
20 2 percent or less by weight when a listing of such
21 ingredients is placed at the end of the ingredients
22 statement following an appropriate quantifying
23 statement, such as ‘contains ____ percent or less of
24 ____’, or ‘less than ____ percent of ____’.

1 “(4) Any disclosure required pursuant to this
2 subsection may be required by appropriate means,
3 except that, notwithstanding any other provision of
4 this act, the Secretary shall not require the listing
5 of any ingredient on any package or in any adver-
6 tisement.

7 “(b) DISCLOSURE OF PERCENTAGE OF DOMESTIC
8 AND FOREIGN TOBACCO.—Not later than 12 months after
9 the effective date of this section, the Secretary shall pro-
10 mulgate regulations that require that each package of a
11 tobacco product disclose, with respect to the tobacco con-
12 tained in that brand—

13 “(1) the percentage of tobacco that is domestic
14 tobacco; and

15 “(2) the percentage of tobacco that is foreign
16 tobacco.

17 “(c) MANDATORY DISCLAIMER.—

18 “(1) Any tobacco product advertising which in-
19 cludes a term classifying a brand of tobacco product
20 according to its ‘tar’ yield or the yield to consumers
21 of any substance, including but not limited to terms
22 such as ‘light’, or ‘low tar’, shall also include the fol-
23 lowing disclaimer: ‘[Brand] not shown to be less
24 hazardous than other [type of tobacco product]’.

25 This section shall not be deemed to apply to the use

1 of the terms ‘filtered’ or ‘filter’. In no event shall
2 any such disclaimer be required on any tobacco
3 product package.

4 “(2) In addition to the provisions of paragraph
5 (1), not later than 12 months after the effective date
6 of this section, the Secretary shall promulgate regu-
7 lations relating to the use of such terms, to ensure
8 that they are not false or misleading.

9 “(3) The Secretary may modify or waive any
10 requirement under this subsection with respect to
11 any product that has been designated by the Sec-
12 retary as a reduced risk product under section
13 912.”.

14 **SEC. 5. REGULATORY RECORD.**

15 Notwithstanding the provisions of subchapter II of
16 chapter 5 of title 5, United States Code, in promulgating
17 regulations under this chapter, the record developed and
18 utilized by the Secretary for the purposes of promulgating
19 subparts (B) and (D) of the regulations relating to the
20 sale, distribution, and use of tobacco products on or about
21 August 28, 1996, as reflected in articles IV and VI of the
22 preamble to the 1996 Food and Drug Administration To-
23 bacco Rule (including public comments, Food and Drug
24 Administration documents, and any other information
25 generated or compiled for purposes of promulgating such

1 regulations), shall be deemed to have the same legal status
2 as if such record had been developed under a rulemaking
3 proceeding conducted pursuant to section 906(d)(1). In all
4 other respects, including with respect to the issue of
5 whether such regulations conform to section 906(d)(1),
6 the procedural requirements of this chapter and the Ad-
7 ministration Procedure Act will apply.

8 **SEC. 6. CONFORMING AND OTHER AMENDMENTS TO GEN-**
9 **ERAL PROVISIONS.**

10 (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND
11 COSMETIC ACT.—Except as otherwise expressly provided,
12 whenever in this section an amendment is expressed in
13 terms of an amendment to, or repeal of, a section or other
14 provision, the reference is to a section or other provision
15 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 301 et seq.).

17 (b) SECTION 301.—Section 301 (21 U.S.C. 331) is
18 amended—

19 (1) in subsection (a), by inserting “tobacco
20 product,” after “device,”;

21 (2) in subsection (b), by inserting “tobacco
22 product,” after “device,”;

23 (3) in subsection (c), by inserting “tobacco
24 product,” after “device,”;

1 (4) in subsection (e), by striking “515(f), or
2 519” and inserting “515(f), 519, or 909”;

3 (5) in subsection (g), by inserting “tobacco
4 product,” after “device,”;

5 (6) in subsection (h), by inserting “tobacco
6 product,” after “device,”;

7 (7) in subsection (j), by striking “708, or 721”
8 and inserting “708, 721, 903, 904, 905, 906, 907,
9 908, 909, 910, or 912”;

10 (8) in subsection (k), by inserting “tobacco
11 product,” after “device,”;

12 (9) by striking subsection (p) and inserting the
13 following:

14 “(p) The failure to register in accordance with section
15 510 or 905, the failure to provide any information re-
16 quired by section 510(j), 510(k), 905(i), or 905(j), or the
17 failure to provide a notice required by section 510(j)(2)
18 or 905(j)(2).”;

19 (10) in subsection (q), by striking paragraph
20 (1) and inserting the following:

21 “(1) The failure or refusal—

22 “(A) to comply with any requirement prescribed
23 under section 518, 520(g), 906(f), or 908;

1 “(B) to furnish any notification or other mate-
2 rial or information required by or under section 519,
3 520(g), 904, 906(f), or 909; or

4 “(C) to comply with a requirement under sec-
5 tion 522.”;

6 (11) in subsection (q)(2), by striking “device,”
7 and inserting “device or tobacco product,”;

8 (12) in subsection (r), by inserting “or tobacco
9 product” after “device” each time that it appears;
10 and

11 (13) by adding at the end the following:

12 “(aa) The sale of tobacco products in violation
13 of a no-tobacco-sale order issued under section
14 303(f).”.

15 (c) SECTION 303.—Section 303(f) (21 U.S.C. 333(f))
16 is amended—

17 (1) by striking the subsection heading and in-
18 serting the following:

19 “(f) CIVIL PENALTIES; NO-TOBACCO-SALE OR-
20 DERS.—”;

21 (2) in paragraph (1)(A), by inserting “or to-
22 bacco products” after “devices”;

23 (3) by redesignating paragraphs (3), (4), and
24 (5) as paragraphs (4), (5), and (6), respectively;

1 (4) by inserting after paragraph (2) the fol-
2 lowing:

3 “(3) If the Secretary finds that a person has
4 committed repeated violations of restrictions promul-
5 gated under section 906(d) at a particular retail out-
6 let then the Secretary may impose a no-tobacco-sale
7 order on that person prohibiting the sale of tobacco
8 products in that outlet. A no-tobacco-sale order may
9 be imposed with a civil penalty under paragraph
10 (1).”;

11 (5) in subparagraph (A) of paragraph (4), as so
12 redesignated—

13 (A) by striking “assessed” the first time it
14 appears and inserting “assessed, or a no-to-
15 bacco-sale order may be imposed,”; and

16 (B) by striking “penalty” and inserting
17 “penalty, or upon whom a no-tobacco-order is
18 to be imposed,”;

19 (6) in subparagraph (B) of paragraph (4), as so
20 redesignated—

21 (A) by inserting after “penalty,” the fol-
22 lowing: “or the period to be covered by a no-to-
23 bacco-sale order,”; and

24 (B) by adding at the end the following: “A
25 no-tobacco-sale order permanently prohibiting

1 an individual retail outlet from selling tobacco
2 products shall include provisions that allow the
3 outlet, after a specified period of time, to re-
4 quest that the Secretary compromise, modify,
5 or terminate the order.”;

6 (7) by adding at the end of paragraph (4), as
7 so redesignated, the following:

8 “(D) The Secretary may compromise, mod-
9 ify, or terminate, with or without conditions,
10 any no-tobacco-sale order.”;

11 (8) in paragraph (5), as so redesignated—

12 (A) by striking “(3)(A)” and inserting
13 “(4)(A)”;

14 (B) by inserting “or the imposition of a
15 no-tobacco-sale order” after “penalty” the first
16 2 places it appears;

17 (C) by striking “issued.” and inserting
18 “issued, or on which the no-tobacco-sale order
19 was imposed, as the case may be.”; and

20 (9) in paragraph (6), as so redesignated, by
21 striking “paragraph (4)” each place it appears and
22 inserting “paragraph (5)”.

23 (d) SECTION 304.—Section 304 (21 U.S.C. 334) is
24 amended—

1 (1) in subsection (a)(2), by striking “and” be-
2 fore “(D)”;

3 (2) in subsection (a)(2), by striking “device.”
4 and inserting a comma and the following:

5 “(E) Any adulterated or misbranded to-
6 bacco product.”;

7 (3) in subsection (d)(1), by inserting “tobacco
8 product,” after “device,”;

9 (4) in subsection (g)(1), by inserting “or to-
10 bacco product” after “device” each place it appears;
11 and

12 (5) in subsection (g)(2)(A), by inserting “or to-
13 bacco product” after “device” each place it appears.

14 (e) SECTION 702.—Section 702(a) (21 U.S.C.
15 372(a)) is amended—

16 (1) by inserting “(1)” after “(a)”; and

17 (2) by adding at the end thereof the following:

18 “(2) For a tobacco product, to the extent feasible,
19 the Secretary shall contract with the States in accordance
20 with paragraph (1) to carry out inspections of retailers
21 in connection with the enforcement of this Act.”.

22 (f) SECTION 703.—Section 703 (21 U.S.C. 373) is
23 amended—

24 (1) by inserting “tobacco product,” after “de-
25 vice,” each place it appears; and

1 (2) by inserting “tobacco products,” after “de-
2 vices,” each place it appears.

3 (g) SECTION 704.—Section 704 (21 U.S.C. 374) is
4 amended—

5 (1) in subsection (a)(1)(A), by inserting “to-
6 bacco products,” after “devices,” each place it ap-
7 pears;

8 (2) in subsection (a)(1)(B), by inserting “or to-
9 bacco products” after “restricted devices” each place
10 it appears; and

11 (3) in subsection (b), by inserting “tobacco
12 product,” after “device,”.

13 (h) SECTION 705.—Section 705(b) (21 U.S.C.
14 375(b)) is amended by inserting “tobacco products,” after
15 “devices,”.

16 (i) SECTION 709.—Section 709 (21 U.S. C. 379) is
17 amended by inserting “or tobacco product” after “device”.

18 (j) SECTION 801.—Section 801 (21 U.S.C. 381) is
19 amended—

20 (1) in subsection (a), by inserting “tobacco
21 products,” after “devices,” the first time it appears;

22 (2) in subsection (a), by inserting “or sub-
23 section (j) of section 905” after “section 510”;

1 (3) in subsection (a), by striking “drugs or de-
2 vices” each time it appears and inserting “drugs, de-
3 vices, or tobacco products”; and

4 (4) in subsection (e)(1), by inserting ‘tobacco
5 product’ after ‘device’.

6 (k) SECTION 1003.—Section 1003(d)(2)(C) (as re-
7 designated by section 101(a)) is amended—

8 (1) by striking “and” after “cosmetics,”; and

9 (2) inserting a comma and “and tobacco prod-
10 ucts” after “devices”.

11 (l) EFFECTIVE DATE FOR NO-TOBACCO-SALE
12 ORDER AMENDMENTS.—The amendments made by sub-
13 section (c), other than the amendment made by paragraph
14 (2) thereof, shall take effect only upon the promulgation
15 of final regulations by the Secretary—

16 (1) defining the term “repeated violation”, as
17 used in section 303(f) of the Federal Food, Drug,
18 and Cosmetic Act (21 U.S.C. 333(f)) as amended by
19 subsection (c), by identifying the number of viola-
20 tions of particular requirements over a specified pe-
21 riod of time that constitute a repeated violation;

22 (2) providing for notice to the retailer of each
23 violation at a particular retail outlet;

24 (3) providing that a person may not be charged
25 with repeated violations at a particular retail outlet

1 unless the Secretary has provided notice of previous
2 violations at that outlet;

3 (4) establishing a period of time during which,
4 if there are no violations by a particular retail out-
5 let, that outlet will not be considered to have been
6 the site of repeated violations when the next viola-
7 tion occurs; and

8 (5) providing that good faith reliance on false
9 identification does not constitute a violation of any
10 minimum age requirement for the sale of tobacco
11 products.

12 **SEC. 7. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

13 Section 4 of the Federal Cigarette Labeling and Ad-
14 vertising Act (15 U.S.C. 1333) is amended to read as fol-
15 lows:

16 **“SEC. 4. LABELING.**

17 **“(a) LABEL REQUIREMENTS.—**

18 **“(1) IN GENERAL.—**It shall be unlawful for any
19 person to manufacture, package, or import for sale
20 or distribution within the United States any ciga-
21 rettes the package of which fails to bear, in accord-
22 ance with the requirements of this section, one of
23 the following labels:

24 **“WARNING: Cigarettes are addictive”**

1 “WARNING: Tobacco smoke can harm your chil-
2 dren”

3 “WARNING: Cigarettes cause fatal lung disease”

4 “WARNING: Cigarettes cause cancer”

5 “WARNING: Cigarettes cause strokes and heart
6 disease”

7 “WARNING: Smoking during pregnancy can harm
8 your baby”

9 “WARNING: Smoking can kill you”

10 “WARNING: Tobacco smoke causes fatal lung dis-
11 ease in non-smokers”

12 “WARNING: Quitting smoking now greatly reduces
13 serious risks to your health”

14 “(2) PLACEMENT; TYPOGRAPHY; ETC.—

15 “(A) IN GENERAL.—Each label statement
16 required by paragraph (1) shall be located in
17 the upper portion of the front and rear panels
18 of the package, directly on the package under-
19 neath the cellophane or other clear wrapping.
20 Except as provided in subparagraph (B), each
21 label statement shall comprise at least the top
22 25 percent of the front and rear panels of the
23 package. The word “WARNING” shall appear
24 in capital letters and all text shall be in con-
25 spicuous and legible 17-point type, unless the

1 text of the label statement would occupy more
2 than 70 percent of such area, in which case the
3 text may be in a smaller conspicuous and leg-
4 ible type size, provided that at least 60 percent
5 of such area is occupied by required text. The
6 text shall be black on a white background, or
7 white on a black background, in a manner that
8 contrasts, by typography, layout, or color, with
9 all other printed material on the package, in an
10 alternating fashion under the plan submitted
11 under subsection (b)(4).

12 “(B) FLIP-TOP BOXES.—For any cigarette
13 brand package manufactured or distributed be-
14 fore January 1, 2000, which employs a flip-top
15 style (if such packaging was used for that
16 brand in commerce prior to June 21, 1997), the
17 label statement required by paragraph (1) shall
18 be located on the flip-top area of the package,
19 even if such area is less than 25 percent of the
20 area of the front panel. Except as provided in
21 this paragraph, the provisions of this subsection
22 shall apply to such packages.

23 “(3) DOES NOT APPLY TO FOREIGN DISTRIBU-
24 TION.—The provisions of this subsection do not
25 apply to a tobacco product manufacturer or dis-

1 tributor of cigarettes which does not manufacture,
2 package, or import cigarettes for sale or distribution
3 within the United States.

4 “(b) ADVERTISING REQUIREMENTS.—

5 “(1) IN GENERAL.—It shall be unlawful for any
6 tobacco product manufacturer, importer, distributor,
7 or retailer of cigarettes to advertise or cause to be
8 advertised within the United States any cigarette
9 unless its advertising bears, in accordance with the
10 requirements of this section, one of the labels speci-
11 fied in subsection (a) of this section.

12 “(2) TYPOGRAPHY, ETC.—Each label statement
13 required by subsection (a) of this section in cigarette
14 advertising shall comply with the standards set forth
15 in this paragraph. For press and poster advertise-
16 ments, each such statement and (where applicable)
17 any required statement relating to tar, nicotine, or
18 other constituent yield shall comprise at least 20
19 percent of the area of the advertisement and shall
20 appear in a conspicuous and prominent format and
21 location at the top of each advertisement within the
22 trim area. The Secretary may revise the required
23 type sizes in such area in such manner as the Sec-
24 retary determines appropriate. The word “WARN-
25 ING” shall appear in capital letters, and each label

1 statement shall appear in conspicuous and legible
2 type. The text of the label statement shall be black
3 if the background is white and white if the back-
4 ground is black, under the plan submitted under
5 paragraph (4) of this subsection. The label state-
6 ments shall be enclosed by a rectangular border that
7 is the same color as the letters of the statements
8 and that is the width of the first downstroke of the
9 capital “W” of the word “WARNING” in the label
10 statements. The text of such label statements shall
11 be in a typeface pro rata to the following require-
12 ments: 45-point type for a whole-page broadsheet
13 newspaper advertisement; 39-point type for a half-
14 page broadsheet newspaper advertisement; 39-point
15 type for a whole-page tabloid newspaper advertise-
16 ment; 27-point type for a half-page tabloid news-
17 paper advertisement; 31.5-point type for a double
18 page spread magazine or whole-page magazine ad-
19 vertisement; 22.5-point type for a 28 centimeter by
20 3 column advertisement; and 15-point type for a 20
21 centimeter by 2 column advertisement. The label
22 statements shall be in English, except that in the
23 case of—

24 “(A) an advertisement that appears in a
25 newspaper, magazine, periodical, or other publi-

1 cation that is not in English, the statements
2 shall appear in the predominant language of the
3 publication; and

4 “(B) in the case of any other advertise-
5 ment that is not in English, the statements
6 shall appear in the same language as that prin-
7 cipally used in the advertisement.

8 “(3) ADJUSTMENT BY SECRETARY.—The Sec-
9 retary may, through a rulemaking under section 553
10 of title 5, United States Code, adjust the format and
11 type sizes for the label statements required by this
12 section or the text, format, and type sizes of any re-
13 quired tar, nicotine yield, or other constituent disclo-
14 sures, or to establish the text, format, and type sizes
15 for any other disclosures required under the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
17 seq.). The text of any such label statements or dis-
18 closures shall be required to appear only within the
19 20 percent area of cigarette advertisements provided
20 by paragraph (2) of this subsection. The Secretary
21 shall promulgate regulations which provide for ad-
22 justments in the format and type sizes of any text
23 required to appear in such area to ensure that the
24 total text required to appear by law will fit within
25 such area.

1 “(4) MARKETING REQUIREMENTS.—

2 “(A) The label statements specified in sub-
3 section (a)(1) shall be randomly displayed in
4 each 12-month period, in as equal a number of
5 times as is possible on each brand of the prod-
6 uct and be randomly distributed in all areas of
7 the United States in which the product is mar-
8 keted in accordance with a plan submitted by
9 the tobacco product manufacturer, importer,
10 distributor, or retailer and approved by the Sec-
11 retary.

12 “(B) The label statements specified in sub-
13 section (a)(1) shall be rotated quarterly in al-
14 ternating sequence in advertisements for each
15 brand of cigarettes in accordance with a plan
16 submitted by the tobacco product manufacturer,
17 importer, distributor, or retailer to, and ap-
18 proved by, the Secretary.

19 “(C) The Secretary shall review each plan
20 submitted under subparagraph (B) and approve
21 it if the plan—

22 “(i) will provide for the equal distribu-
23 tion and display on packaging and the ro-
24 tation required in advertising under this
25 subsection; and

1 “(ii) assures that all of the labels re-
2 quired under this section will be displayed
3 by the tobacco product manufacturer, im-
4 porter, distributor, or retailer at the same
5 time.”.

6 **SEC. 8. AUTHORITY TO REVISE CIGARETTE WARNING**
7 **LABEL STATEMENTS.**

8 Section 4 of the Federal Cigarette Labeling and Ad-
9 vertising Act (15 U.S.C. 1333), as amended by section 4,
10 is further amended by adding at the end the following:

11 “(c) CHANGE IN REQUIRED STATEMENTS.—The Sec-
12 retary may, by a rulemaking conducted under section 553
13 of title 5, United States Code, adjust the format, type size,
14 and text of any of the warning label statements required
15 by subsection (a) of this section subject to the limitation
16 on proportional size of the warning contained in sub-
17 sections (a)(2) and (b)(2), or establish the format, type
18 size, and text of any other disclosures required under the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
20 et seq.), if the Secretary finds that such a change would
21 promote greater public understanding of the risks associ-
22 ated with the use of smokeless tobacco products.”.

1 **SEC. 9. SMOKELESS TOBACCO LABELS AND ADVERTISING**
2 **WARNINGS.**

3 Section 3 of the Comprehensive Smokeless Tobacco
4 Health Education Act of 1986 (15 U.S.C. 4402) is amend-
5 ed to read as follows:

6 **“SEC. 3. SMOKELESS TOBACCO WARNING.**

7 **“(a) GENERAL RULE.—**

8 **“(1) It shall be unlawful for any person to man-**
9 **ufacture, package, or import for sale or distribution**
10 **within the United States any smokeless tobacco**
11 **product unless the product package bears, in accord-**
12 **ance with the requirements of this Act, one of the**
13 **following labels:**

14 **“WARNING: This product can cause mouth cancer”**

15 **“WARNING: This product can cause gum disease**
16 **and tooth loss”**

17 **“WARNING: This product is not a safe alternative**
18 **to cigarettes”**

19 **“WARNING: Smokeless tobacco is addictive”**

20 **“(2) Each label statement required by para-**
21 **graph (1) shall be—**

22 **“(A) located on the 2 principal display**
23 **panels of the package, and each label statement**
24 **shall comprise at least 25 percent of each such**
25 **display panel; and**

1 “(B) in 17-point conspicuous and legible
2 type and in black text on a white background,
3 or white text on a black background, in a man-
4 ner that contrasts by typography, layout, or
5 color, with all other printed material on the
6 package, in an alternating fashion under the
7 plan submitted under subsection (b)(3), except
8 that if the text of a label statement would oc-
9 cupy more than 70 percent of the area specified
10 by subparagraph (A), such text may appear in
11 a smaller type size, so long as at least 60 per-
12 cent of such warning area is occupied by the
13 label statement.

14 “(3) The label statements required by para-
15 graph (1) shall be introduced by each tobacco prod-
16 uct manufacturer, packager, importer, distributor, or
17 retailer of smokeless tobacco products concurrently
18 into the distribution chain of such products.

19 “(4) The provisions of this subsection do not
20 apply to a tobacco product manufacturer or dis-
21 tributor of any smokeless tobacco product that does
22 not manufacture, package, or import smokeless to-
23 bacco products for sale or distribution within the
24 United States.

25 “(b) REQUIRED LABELS.—

1 “(1) It shall be unlawful for any tobacco prod-
2 uct manufacturer, packager, importer, distributor, or
3 retailer of smokeless tobacco products to advertise or
4 cause to be advertised within the United States any
5 smokeless tobacco product unless its advertising
6 bears, in accordance with the requirements of this
7 section, one of the labels specified in subsection (a).

8 “(2) Each label statement required by sub-
9 section (a) in smokeless tobacco advertising shall
10 comply with the standards set forth in this para-
11 graph. For press and poster advertisements, each
12 such statement and (where applicable) any required
13 statement relating to tar, nicotine, or other con-
14 stituent yield shall—

15 “(A) comprise at least 20 percent of the
16 area of the advertisement, and the warning area
17 shall be delineated by a dividing line of con-
18 trasting color from the advertisement; and

19 “(B) the word “WARNING” shall appear
20 in capital letters and each label statement shall
21 appear in conspicuous and legible type. The text
22 of the label statement shall be black on a white
23 background, or white on a black background, in
24 an alternating fashion under the plan submitted
25 under paragraph (3).

1 “(3)(A) The label statements specified in sub-
2 section (a)(1) shall be randomly displayed in each
3 12-month period, in as equal a number of times as
4 is possible on each brand of the product and be ran-
5 domly distributed in all areas of the United States
6 in which the product is marketed in accordance with
7 a plan submitted by the tobacco product manufac-
8 turer, importer, distributor, or retailer and approved
9 by the Secretary.

10 “(B) The label statements specified in sub-
11 section (a)(1) shall be rotated quarterly in alter-
12 nating sequence in advertisements for each brand of
13 smokeless tobacco product in accordance with a plan
14 submitted by the tobacco product manufacturer, im-
15 porter, distributor, or retailer to, and approved by,
16 the Secretary.

17 “(C) The Secretary shall review each plan sub-
18 mitted under subparagraph (B) and approve it if the
19 plan—

20 “(i) will provide for the equal distribution
21 and display on packaging and the rotation re-
22 quired in advertising under this subsection; and

23 “(ii) assures that all of the labels required
24 under this section will be displayed by the to-

1 bacco product manufacturer, importer, dis-
2 tributor, or retailer at the same time.

3 “(c) TELEVISION AND RADIO ADVERTISING.—It is
4 unlawful to advertise smokeless tobacco on any medium
5 of electronic communications subject to the jurisdiction of
6 the Federal Communications Commission.”.

7 **SEC. 10. AUTHORITY TO REVISE SMOKELESS TOBACCO**
8 **PRODUCT WARNING LABEL STATEMENTS.**

9 Section 3 of the Comprehensive Smokeless Tobacco
10 Health Education Act of 1986 (15 U.S.C. 4402), as
11 amended by section 6, is further amended by adding at
12 the end the following:

13 “(d) AUTHORITY TO REVISE WARNING LABEL
14 STATEMENTS.—The Secretary may, by a rulemaking con-
15 ducted under section 553 of title 5, United States Code,
16 adjust the format, type size, and text of any of the warn-
17 ing label statements required by subsection (a) of this sec-
18 tion, subject to the limitations on proportional size of the
19 warning contained in paragraphs (2) and (3) of subsection
20 (a), or establish the format, type size, and text of any
21 other disclosures required under the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 301 et seq.), if the Secretary
23 finds that such a change would promote greater public un-
24 derstanding of the risks associated with the use of smoke-
25 less tobacco products.”.

1 **SEC. 11. TAR, NICOTINE, AND OTHER SMOKE CONSTITUENT**
2 **DISCLOSURE TO THE PUBLIC.**

3 Section 4(a) of the Federal Cigarette Labeling and
4 Advertising Act (15 U.S.C. 1333(a)), as amended by sec-
5 tion 4, is further amended by adding at the end the fol-
6 lowing:

7 “(4)(A) The Secretary shall, by a rulemaking
8 conducted under section 553 of title 5, United
9 States Code, determine (in the Secretary’s sole dis-
10 cretion) whether cigarette and other tobacco product
11 manufacturers shall be required to include in the
12 area of each cigarette advertisement specified by
13 subsection (b) of this section, or on the package
14 label, or both, the tar and nicotine yields of the ad-
15 vertised or packaged brand. Any such disclosure
16 shall be in accordance with the methodology estab-
17 lished under such regulations, shall conform to the
18 type size requirements of subsection (b) of this sec-
19 tion, and shall appear within the area specified in
20 subsection (b) of this section.

21 “(B) Any differences between the requirements
22 established by the Secretary under subparagraph (A)
23 and tar and nicotine yield reporting requirements es-
24 tablished by the Federal Trade Commission shall be
25 resolved by a memorandum of understanding be-

1 tween the Secretary and the Federal Trade Commis-
2 sion.

3 “(C) In addition to the disclosures required by
4 subparagraph (A) of this paragraph, the Secretary
5 may, under a rulemaking conducted under section
6 553 of title 5, United States Code, prescribe disclo-
7 sure requirements regarding the level of any ciga-
8 rette or other tobacco product smoke constituent.
9 Any such disclosure may be required if the Secretary
10 determines that disclosure would be of benefit to the
11 public health, or otherwise would increase consumer
12 awareness of the health consequences of the use of
13 tobacco products, except that no such prescribed dis-
14 closure shall be required on the face of any cigarette
15 package or advertisement. Nothing in this section
16 shall prohibit the Secretary from requiring such pre-
17 scribed disclosure through a cigarette or other to-
18 bacco product package or advertisement insert, or by
19 any other means under the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 301 et seq.).”

21 **SEC. 12. REGULATION REQUIREMENT.**

22 (a) TESTING, REPORTING, AND DISCLOSURE.—Not
23 later than 24 months after the date of enactment of this
24 Act, the Secretary, through the Commissioner of the Food
25 and Drug Administration, shall promulgate regulations

1 under the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 301 et seq.) that meet the requirements of sub-
3 section (b) of this section.

4 (b) CONTENTS OF RULES.—The rules promulgated
5 under subsection (a) shall require the testing, reporting,
6 and disclosure of tobacco product smoke constituents and
7 ingredients that the Secretary determines should be dis-
8 closed to the public in order to protect the public health.
9 Such constituents shall include tar, nicotine, carbon mon-
10 oxide, and such other smoke constituents or ingredients
11 as the Secretary may determine to be appropriate. The
12 rule may require that tobacco product manufacturers,
13 packagers, or importers make such disclosures relating to
14 tar and nicotine through labels or advertising, and make
15 such disclosures regarding other smoke constituents or in-
16 gredients as the Secretary determines are necessary to
17 protect the public health.

18 (c) AUTHORITY.—The Food and Drug Administra-
19 tion shall have authority to conduct or to require the test-
20 ing, reporting, or disclosure of tobacco product smoke con-
21 stituents.

22 **SEC. 13. FTC JURISDICTION NOT AFFECTED.**

23 (a) IN GENERAL.—Except where expressly provided
24 in this Act, nothing in this Act shall be construed as lim-
25 iting or diminishing the authority of the Federal Trade

1 Commission to enforce the laws under its jurisdiction with
2 respect to the advertising, sale, or distribution of tobacco
3 products.

4 (b) ENFORCEMENT BY FTC.—Any advertising that
5 violates this Act is an unfair or deceptive act or practice
6 under section 5(a) of the Federal Trade Commission Act
7 (15 U.S.C. 45(a)) and shall be considered a violation of
8 a rule promulgated under section 18 of that Act (15
9 U.S.C. 57a).

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